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EPA

Federal Activities in Toxic Substances

Toxic Integration Information Series

federal register

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Reprint/revision of 1981 document -- describes the toxic substances regulatory activities of 22 offices in 8 Federal agencies or departments. The document covers the breakdown of each organization, summarizes the statutory authorities, highlights regulatory development processes, and describes the various toxics-related programs and activities. There is also a graphic summary of 14 major statutes involved with controlling toxic substances.

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Toxics Integration Information Series

FEDERAL ACTIVITIES
IN
TOXIC SUBSTANCES

Edited by

Catherine Allin
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Office of Pesticides and Toxic Substances

U.S. Environmental Protection Agency

September 1983

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FOREWORD

In 1976, one of the most comprehensive pieces of Federal environmental legislation, the Toxic Substances Control Act (TSCA), was enacted. TSCA was designed to address both the overlaps and the gaps in existing health and environmental legislation. The Act provides broad authority to the Environmental Protection Agency (EPA) to regulate the thousands of chemicals in commerce. TSCA directs EPA to take appropriate regulatory action if any of these chemicals are found to present an unreasonable risk to human health or the environment. When signing TSCA into law, the President stated that, "[TSCA] closes a gap in our current array of laws to protect the health of our people and the environment." He spoke of the various mandates of current environmental statutes and concluded that "none of the existing statutes provide(s) comprehensive protection." This is what TSCA was designed to do.

Because of the comprehensive authority of TSCA, Congress recognized that the potential existed for duplicative regulatory action. For this reason, Section 9 of TSCA directs EPA to integrate and coordinate the various Federal activities involved with controlling toxic substances whenever regulatory action is contemplated or initiated under this Act.

There are nearly two dozen Federal statutes governing toxic substances as well as a comparable number of Federal agencies responsible for the research, regulatory, and advisory provisions of these various acts. Effective integration of toxic substances activities requires an awareness and comprehension of the many Federal statutes involved as well as an understanding of the organizational structure and relevant activities of the agencies responsible for implementing these statutes.

This document is an outgrowth of the efforts on the part of EPA's Chemical Coordination Staff to develop the knowledge and expertise needed to integrate and coordinate Federal toxic substances regulatory activities. During the process of familiarizing ourselves with the relevant Federal statutes and agencies, we concluded that much of the information we had been gathering was also of interest to others. Therefore, we decided to publish the material in a readily usable format and make it available to a wider audience.

In this second edition five new offices have been added for a total of 22 offices located within 8 Federal agencies or departments which, in our judgment, have a primary role in the control of toxic substances. Because this field is quite new and rapidly expanding, we recognize that much of the material presented here may quickly become outdated. Therefore, it is anticipated that this document will be updated annually, and future editions will include additional agencies and statutes. We welcome any suggestions for improving and/or expanding this material.

A brief note on the format may be helpful in using this publication. The information on each office is divided into several sections. The first section describes the organization of the office and highlights those divisions, branches, etc., which are concerned with toxic substances. The second section summarizes the statutory authority for the office and briefly explains those subsections of the statute which pertain to toxics. The third section (for regulatory agencies only) highlights the regulatory development process followed by that agency. The final section briefly describes the various toxics-related programs and activities.

We have also included an Appendix which provides a graphic summary of 14 major statutes involved with controlling toxic substances. The first 3 charts in the Appendix focus on 8 categories of exposure pathways and the fourth chart summarizes the major information-gathering/producing provisions of the 14 statutes.

This publication would not have been possible without the cooperation and support of staff members in the various agencies and offices covered herein. Their assistance and encouragement were instrumental in guiding the manuscript through several stages of preparation. We deeply appreciate and gratefully acknowledge this assistance.

Any comments or suggestions you may have should be directed to:

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OTHER PUBLICATIONS IN THE TOXICS INTEGRATION POLICY SERIES:

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(July 1981) EPA-560/TIP-81-001; PB81-242406

Measuring and Comparing the Cost-Effectiveness of EPA
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Risks - Volume 1, Feasibility Study (June 1981)
EPA 560/TIIS-82-007

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EPA-560/TIIS-82; PB83-130294

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EPA-560/13-79-003

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(December 1980) EPA-560/13-80-040(a), PB81-176414;
EPA-13-80-040(b), PB81-176422

EPA Chemical Activities Status Report - 3rd Edition (June 1982)
EPA-560/TIIS-82-002a, -002b

Chemical Selection Methods: An Annotated Bibliography -
2nd Edition (March 1983) EPA-560/TIIS-83-003

Chemical Substances Designation (December 1981)
EPA-560/TIIS-82-003, PB83-130294; -004, PB83-13032; -005,
PB83-130310; -006; PB83-130328

Directory of Federal Coordinating Groups for Toxic Substances -
1st Edition (June 1979) EPA-560/13-80-008; PB80-137870

Directory of Federal Coordinating Groups for Toxic Substances -
2nd Edition (March 1980) PB80-177314

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for Toxic Substances - 3rd Edition (May 1983)
EPA-560/TIIS-83-004

Perspectives on the Top 50 Production Volume Chemicals (July 1980) EPA-560/13-80-27; PB80-221682

TSCA Status Report for Existing Chemicals Volume 1, Issue 2 (July 1980) EPA-560/13-80-033

TSCA Status Report for Existing Chemicals Volume 2, Issue 2 (July 1981) EPA-560/TIIS-81-004

Chemical Selection Methods: An Annotated Bibliography (November 1980) EPA-560/TIIS-80-001; PB81-241481

Chemical Information Resources Handbook (January 1981) EPA-560/TIIS-81-002; PB82-225657 -- 2nd edition (September 1983), EPA 560/TIIS-83-006

Toxic Substances Control Act Grants to States (July 1981) EPA-560/TIIS-81-003; PB81-232969

TSCA Chemicals in Commerce Inventory: Regional and State Perspectives (August 1981) EPA-560/TIIS-81-005

State Integrated Toxics Management: 20 Profiles (Reprint August 1983) EPA-560/TIIS-83-005

Overview of the Industry File Index System (June 1983) EPA-560/TIIS-83-002

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FEDERAL AGENCIES

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Washington, D.C. 20207

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Information: 301-492-6957

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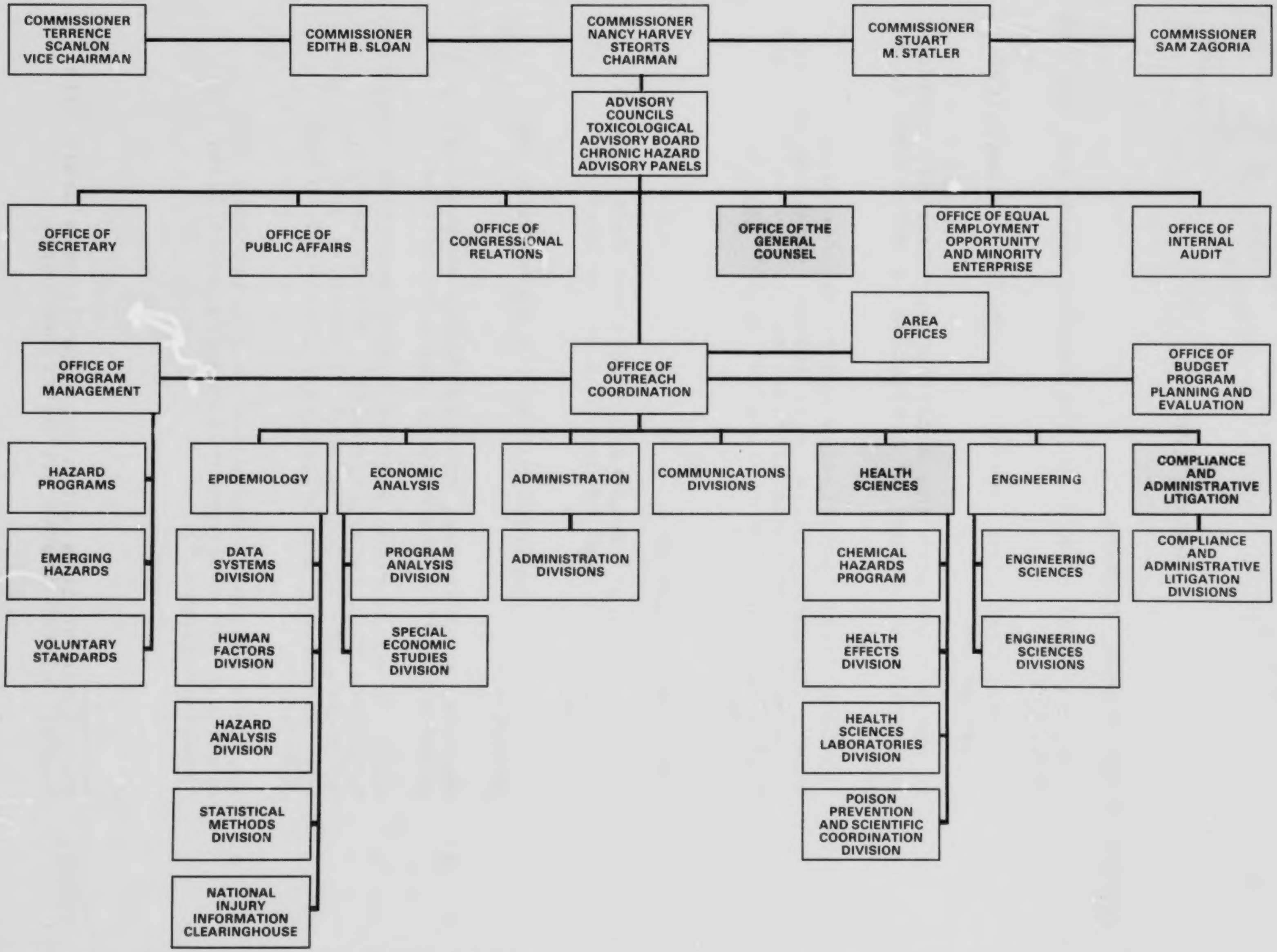
The U.S. Consumer Product Safety Commission (CPSC), established May 14, 1973 as an independent regulatory agency, is charged with reducing unreasonable risks of injury associated with consumer products. The Commission is responsible for implementing the Consumer Product Safety Act, the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, the Flammable Fabrics Act, and the Refrigerator Safety Act.

The Commission issues and enforces mandatory safety standards, helps industry develop voluntary safety standards, and bans unsafe products when safety standards are not feasible. It also monitors recalls of defective products, informs and educates consumers about product hazards, conducts research and develops test methods, collects and publishes injury and hazard data, and promotes uniform product regulations by governmental units.

CPSC is headed by five Commissioners appointed by the President with the advice and consent of the Senate.

CONSUMER PRODUCT SAFETY COMMISSION
ORGANIZATIONAL CHART*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PROGRAM ANALYSIS DIVISION
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ADMINISTRATION
ADMINISTRATION DIVISIONS
COMMUNICATIONS DIVISIONS
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ENGINEERING SCIENCES
ENGINEERING SCIENCES DIVISIONS
COMPLIANCE AND ADMINISTRATIVE LITIGATION
COMPLIANCE AND ADMINISTRATIVE LITIGATION DIVISIONS

***NOTE: A partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.**

ORGANIZATION*

OFFICE OF THE GENERAL COUNSEL

- Provides legal counsel to the Commissioners and staff of CPSC.
- Furnishes CPSC with relevant scientific and technical expertise.
- In conjunction with the Department of Justice, conducts or supervises conduct of litigation in which CPSC is a party.
- Provides final legal review and recommendations on safety standards, rules, regulations, petition actions, procurements, personnel and administrative actions, and drafts documents for publication in the Federal Register.

OFFICE OF PROGRAM MANAGEMENT

- Supervises hazard-related programs delineated in the CPSC operating plan or assigned by the Executive Director.
- Exercises program review over the progression of projects.
- Manages, coordinates, and recommends corrective adjustments to maintain Commission priorities.
- Works in conjunction with Associate Executive Directors to ensure that legal, technical, environmental, economic, and social impacts of projects are comprehensively and objectively presented to the Commission.
- Provides continual direction to all projects (for chemicals and environmental hazards activities, see "Health Sciences.")

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*Note: Only those offices which customarily have dealt with toxics-related issues are described here.

EPIDEMIOLOGY

- Provides professional expertise and analysis of the role of human interaction with toxic substances. Aids in developing information on scenarios for use in establishing product safety standards for toxic substances.
- Collects injury data and prepares injury data analysis to identify hazards, hazard patterns and human factor analysis.

ECONOMIC ANALYSIS

- Collects data on the chemical ingredients of consumer products.
- Provides information required for evaluating the economic effect of various options for reducing the unreasonable risks of injury associated with some consumer products.

ENGINEERING

- Develops and evaluates product safety standards and test methods.
- Furnishes relevant scientific and technical expertise.

HEALTH SCIENCES

- Provides scientific and technical expertise in the chemical, biological, toxicological, physiological, medical, and other health-related sciences.
- Collects data and assesses needs for product safety standards.
- Develops and evaluates performance criteria, quality control standards, and test methods.
- Conducts compliance testing and provides technical supervision to CPSC field chemical laboratories.

- Serves as Secretariat for National Poison Prevention Week.
- Provides program management for acute and chronic chemical and environmental hazards activities.

COMPLIANCE AND ADMINISTRATIVE LITIGATION

- Supervises surveillance and enforcement policy, legal case quality, productivity, planning input, and review.
- Identifies and acts on any defective consumer product already in distribution.
- Evaluates industry compliance with existing safety standards.
- Conducts enforcement litigation.
- Provides legal advice and case guidance to CPSC field offices.
- Participates in the development of standards prior to promulgation.

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800 638-8333 (Alaska, Hawaii, Virgin Islands only)

STATUTORY AUTHORITIES

Consumer Product Safety Act

15 U.S.C. §§2051 et seq.

The Consumer Product Safety Act (CPSA) grew out of a desire for a less fragmented approach to the regulation of the safety of consumer products. Prior to 1973, several agencies had authority over different aspects of consumer product safety. The Consumer Product Safety Act established the Consumer Product Safety Commission as an independent regulatory commission and also gave the Commission responsibility for the Federal Hazardous Substances Act (FHSA), the Poison Prevention Packaging Act of 1970 (PPPA), the Flammable Fabrics Act (FFA), and the Refrigerator Safety Act (RSA).

The purposes of the CPSA are to assist consumers in evaluating the comparative safety of consumer products, to protect the public against unreasonable risks of injury associated with consumer products, to develop uniform safety standards for consumer products, to minimize conflicting State and local regulations, and to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.

Key Sections of Act--Toxic Focus

sec. 5(a)	Requires Commission to maintain an injury information clearinghouse on hazards associated with consumer products.
sec. 6	Provides procedures for disclosure of information obtained by the Commission.
sec. 7	Provides authority to promulgate consumer product safety standards in order to prevent risks of injury associated with consumer products. The standard can consist of performance requirements or requirements for labeling with clear warnings or instructions. Voluntary standards must be relied on if they would be adequate.
sec. 8	Provides authority for banning consumer products that present an unreasonable risk of injury and for which no standard is feasible.

sec. 9	Details administrative procedures for promulgation of consumer product safety rules.
sec. 12	Empowers the Commission to seek immediate court action against imminently hazardous consumer products.
sec. 14	Requires manufacturers of consumer products to certify conformity to CPSC safety standards.
sec. 15	Authorizes the Commission to require manufacturers of hazardous products to take certain actions (notification and repair, replacement, or refund).
sec. 26	Provides for the appointment of Chronic Hazard Advisory Panels.
sec. 30(d)	Gives the Commission the authority to regulate risks of injury under this act rather than FHSA, PPPA, or FFA, if the Commission finds it by Rule to be in the public interest.

Regulatory Options Available Under Statute

- Assisting in voluntary standards development
- Issuing mandatory standards
- Ordering, remove or recall of products
- Banning

Federal Hazardous Substances Act
15 U.S.C. §§1261 et seq.

The Federal Hazardous Substances Act (FHSA) was enacted in 1960, as a labeling law. The original law established definitions for toxic, corrosive, irritant, flammable, and radioactive substances. Materials that met the definitions were required to bear cautionary labeling. Subsequently, two provisions were added that permit the banning of certain household substances. A hazardous household substance can be banned by regulation under FHSA if the Commission decides that the degree or nature of the hazard involved warrants removal of such substance from interstate commerce because no cautionary labeling that could be required under the Act would be adequate to address the hazard. If the substance is deemed to pose an imminent hazard to public health, the Commission can prevent its distribution in interstate commerce upon publication of a Federal Register notice of imminent hazard pending the completion of the rulemaking proceedings.

Key Sections of Act--Toxics Focus

sec. 2	Establishes definitions for hazardous substances and requires substances which meet the definitions to be labeled. Authorizes banning of hazardous substances where the nature and degree of the hazard is such that no possible labeling would be adequate to protect the public health and safety.
sec. 3	Allows the Commission to declare products hazardous and to require special labeling.
sec. 4	Outlines illegal acts under the Federal Hazardous Substances Act.
sec. 5-8	Gives the Commission authority to seek penalties, seizures, and injunctions.
sec. 10	Gives the Commission authority to promulgate regulations for efficient enforcement of this act.
sec. 15	Authorizes the repurchase of certain banned hazardous substances.
sec. 20	Directs the CPSC to establish the Toxicological Advisory Board to give scientific and technical advice to the Commission.

Regulatory Options Available Under Statute

- Declaring products to be hazardous substances which must be labeled in accordance with the Act
- Requiring special labeling for hazardous household substances
- Banning hazardous household substances
- Requiring the repurchase of banned hazardous substances.

Poison Prevention Packaging Act of 1970
15 U.S.C. §§1471 et seq.

Administration of the Poison Prevention Packaging Act of 1970 (PPPA) was transferred to the Commission from the Food and Drug Administration in 1973. Under this Act, the Commission can establish standards for special packaging of household substances in order to protect children from handling, using, or ingesting hazardous substances. Products that can be regulated under PPPA include products covered by the Federal Hazardous Substances Act as well as food, drugs, cosmetics, and fuels in portable containers.

Key Sections of Act--Toxics Focus

sec. 3	Gives the Commission authority to establish special packaging standards for hazardous household substances.
sec. 4	Authorizes manufacturers to supply noncomplying products in a single size especially for use by elderly or handicapped persons.
sec. 5	Establishes requirements for proceedings to issue, amend, or repeal a regulation prescribing a standard.

Regulatory Options Available Under Statute

- Establishing special packaging standards
- Establishing exemptions from special packaging standards for particular substances

REGULATORY DEVELOPMENT

REGULATORY PROCESS

1. Identification of "candidate product" for regulatory development:
    - Internal--data gathering and analysis.
    - External--Commission receives petition.

2. Development of strategy:

   - Conduct relevant analyses.
   - Satisfy Section 9 (CPSA) requirements preliminarily--assessment of economic impact of proposed regulation; must show that regulation will reduce "unreasonable risk" and that an adequate voluntary standard does not exist.
   - Convene and obtain findings of a Chronic Hazard Advisory Panel (for chemical chronic hazards only).

3. Preparation of briefing package by Program Manager and drafting of advance notice of proposed rulemaking by the Office of General Counsel.

4. Review of briefing package and advance proposed rulemaking.

5. Revision of briefing package and advance notice of proposed rulemaking.

6. Approval of advance notice of proposed rulemaking. Solicitation of public comments.

7. Review of public comments, development of proposed regulation, solicitation of public comments, development of final rule approval by Commission, promulgation of final rule, and commencement of enforcement activities.

EXISTING REGULATIONS

Consumer Product Safety Act	16 CFR 1000-1404
Federal Hazardous Substances Act	16 CFR 1500-1512
Flammable Fabrics Act	16 CFR 1700-1704
Refrigerator Safety Act	16 CFR 1750

TOXICS-RELATED ACTIVITIES

The Consumer Product Safety Commission addresses toxic substances through its Directorate for Health Sciences. Within the Directorate, activities fall within two major areas, the Chemical Hazards Program and Health Sciences Support.

I. Chemical Hazards Program

The goal of the Chemical Hazards Program is to reduce the number of deaths, injuries, and illnesses resulting from consumer exposure to hazardous chemicals in consumer products. To achieve this goal, the program strives to meet two objectives. First, the Commission attempts to limit exposure to hazardous chemicals in consumer products which may have acute effects, such as burns, poisonings and deaths. In 1980, an estimated 383,000 people, including 131,000 children under 5 years of age, were treated in hospital emergency rooms for acute injuries associated with chemical consumer products. The estimated social costs attributable to these injuries were in excess of $500 million. The second objective is to limit exposure to hazardous chemicals which may cause chronic adverse health effects, such as cancer, neurotoxic disorders, birth defects, and deaths. A 1981 report by the Office of Technology Assessment of the Congress estimated that perhaps as many as 15,000 new cancers and 8,000 cancer deaths every year may be associated with exposure to carcinogens in consumer products. The Chemical Hazards Program also strives to reduce exposure to hazardous chemicals in the indoor air. The chemicals may be emitted from building materials or furnishings, from household cleaning and craft products, and from unvented heating and cooking appliances.

To meet its objectives, the Commission:

- identifies potentially hazardous chemicals used in consumer products;
- determines the toxicity of the identified chemicals, the amount of the chemicals present in consumer products, the extent of consumer exposure through the indoor air and through foreseeable use or misuse of the products, and the marketing patterns of those products. This information allows the Commission to judge the potential risk posed to consumers by the chemicals;
- develops options for reducing consumer exposure to hazardous chemicals and indoor air pollutants, and utilizes efforts of other agencies whenever possible.

The Commission uses hazard assessments prepared by other government agencies and participates in the National Toxicology Program to supplement its resources and minimize duplication of effort in dealing with acute and chronic chemical hazards.

A. FY 1983 and FY 1984 Activities

- Poison Prevention

  - PPPA Exemptions. In FY 1983, the Commission completed action to grant exemptions for oral contraceptives dispensed in specific types of packaging. The Commission also made a final decision to continue the policy of exemptions for promotional samples of prescription drugs which are distributed to physicians. In FY 1984, the Commission will complete action on a petition to exempt hormonal products containing conjugated estrogens, and will consider other formal requests from industry for exemptions under the PPPA.

  - PPPA Protocol Testing. To comply with the PPPA, industry often tests packaging to ensure that it is child-resistant, but not overly difficult for adults to use properly. The test procedures which have been used since enactment of the PPPA are quite costly and complex. In addition, the test protocol does not include adults over age 45. Older consumers often have difficulty using child-resistant packaging and, consequently, abuse or misuse the packaging in the home. In FY 1983, the Commission published, for public comment, an Advance Notice of Proposed Rulemaking to revise the PPPA test protocol. These revisions are meant to reduce the testing burden in time and cost for industry, and to provide for the inclusion of older adults in the test process. In FY 1984, verification tests will be conducted.

  - Special Packaging Evaluation. In FY 1983, the Commission proposed a regulation, under the PPPA, to require child-resistant packaging for over-the-counter products containing diphenhydramine. In FY 1984, the Commission will complete action on diphenhydramine, and will complete evaluation of injury data to determine if special packaging is needed for petroleum distillates, and topical drug products.

- Pharmacy/Medical Community Awareness. In FY 1983, the Commission worked with State Boards of Pharmacy, and other state organizations, to bolster enforcement of child-resistant packaging dispensing practices, and developed a draft text on poison prevention packaging for pharmacy and medical students to increase their awareness of ingestion hazards. In FY 1984, the Commission will pilot test and complete development of the PPPA test, and will negotiate Memoranda of Understanding with individual states, providing for state administration and enforcement of the PPPA prescription drug regulation.

  - Dual Purpose Packaging. It is estimated that up to 20 percent of child-resistant packaging by FY 1984 will use dual purpose closures (that is, closures which can be used in a child-resistant or non child-resistant mode). This usage may lead to increased accidental poisonings of children. In FY 1983, the Commission completed development and evaluation of proposals for a pilot study to assess the impact of dual purpose packaging, and initiated a consumer survey of accidental ingestion incidents. In FY 1984 the Commission will complete the consumer survey, and will consider whether or not further action is warranted.

- Strong Sensitizers. Certain chemicals cause a severe reaction in susceptible individuals. The Commission currently requires special labeling for only five such substances, which are present in consumer products. In FY 1983, the commission conducted in-depth reviews of the literature on human sensitization to nickel, chromium, colophony and PTBP-F. It completed action to revise the definition of "strong sensitizer" under the Federal Hazardous Substances Act, and initiated steps to set up an advisory panel to review the Commissioner's recommendations regarding strong sensitizers. During the year, the Commission awarded a contract to obtain data on exposure levels and thresholds of sensitization reaction in humans for a variety of chemicals will be undertaken in FY 1984, and existing labeling requirements will be modified, if warranted.

- Potassium Dichromate. In FY 1983, the Commission considered, and took appropriate action on a petition to ban potassium dichromate for use in home humidifiers.

- Emerging Chemical Hazards. In FY 1983 the Commission prepared over 60 preliminary and 20 in-depth economic reports and more than 10 preliminary and in-depth toxicity assessments of chemicals in the computerized data system for tracking emerging chemical hazards (STIC). It also completed preliminary recommendation reports for over 25 chemicals; these reports combine preliminary economic and toxicity assessments and recommend further activity, when appropriate, on toxic chemicals in consumer products. A conversion of the data system for tracking chemicals into a new data processing program was completed in FY 1983. Monitoring major sources of toxicity data for chronic chemical hazards in consumer products and up-dating the STIC data base will continue in FY 1984.

- Dyes and Finishes. In FY 1983 the Commission completed its study of benzidine congener dyes. It found the economic importance of these dyes to be decreasing: the use of these dyes is being discontinued in consumer dye products and commercial textile applications. The amount of dye likely to be inhaled during consumer use was found to be significantly less than previously believed, and experiments indicate the dyes do not penetrate the skin in measurable amounts. The review and testing of other potentially hazardous dyes and consumer exposure to them began in FY 1983 and will continue in FY 1984. More than 20 dyes were studied in-depth in FY 1983, and in addition, 10 to 15 will be similarly analyzed in FY 1984. In FY 1984, the Commission will evaluate consumer exposure to the flame retardant chemical, tris(1,3-dichloroisoproply)phosphate, an animal carcinogen. Other flame retardant finishes to which consumers are exposed will be evaluated for evidence of toxicity.

- Indoor Air Quality. Consumers may be exposed to potentially hazardous chemicals released from various household materials under the jurisdiction of CPSC. The Commission is currently investigating exposure to several substances which may have an adverse effect on indoor air quality.

- Combustion Products. The hazard to the millions of families who use uninvented fuel-fired appliances results from the toxic gases produced by the burning flame. The Commission identified work in this area as a priority in FY 1983, FY 1984 and FY 1985.

  -- Kerosene Heaters. During FY 1983 the Commission completed its testing and health hazard analysis of kerosene heaters and began, in cooperation with the kerosene heater industry and Underwriters Laboratory, to develop a voluntary standard to limit emissions of nitrogen dioxide and carbon monoxide. The industry anticipated that the standard could address units produced for the 1984-85 heating season. The success of the voluntary effort will be evaluated in FY 1985. During FY 1983, the Commission completed an in-depth toxicological evaluation of the health hazards presented by carbon monoxide, nitrogen dioxide, sulfur dioxide and other substances emitted into the indoor air from unvented heaters.

  -- Unvented Gas Space Heaters. During FY 1983, the Commission completed a preliminary hazard evaluation of pollutant emissions from unvented gas space heaters. The analysis concluded that a potential health hazard might exist from anticipated patterns of consumer use. A joint CPSC-industry task group has been formed to coordinate laboratory testing, in-home monitoring studies, consumer use surveys, and pollutant exposure modeling efforts. The final hazard analysis and recommendations will be completed in FY 1984. Voluntary emissions standards, if warranted, will be implemented in FY 1985.

  -- Other Fuel-fired Products. During FY 1984 and FY 1985, concurrent with the on-going investigation and voluntary standards development on unvented gas and kerosene heaters, the Commission will be evaluating new products, e.g., cabinet heaters and catalytic heaters as well as evaluating existing products such as coal and wood burning stoves, and technological improvements made to gas stoves and ovens. Hazard analysis for gas stoves and coal and wood burning stoves are scheduled for completion in FY 1985.

- Asbestos in the Home. Asbestos has been used in a wide variety of products in the home. Some of these products may be deteriorating and releasing asbestos fibers, or the asbestos may be released during remodeling or renovation efforts. In FY 1983, the Commission distributed over 10,000 copies of the consumer information booklet, Asbestos in the Home, to conduct limited monitoring efforts to determine levels of asbestos fibers in the air of homes where fibers are believed to be being emitted.

- Organic Pollutants. Organic pollutants such as toluene and benzaldehyde may be generated in the home during the normal use of some consumer products, and may be emitted from structural materials, furnishings, and combustion sources. In FY 1983, the Commission evaluated information from a monitoring study in 40 homes on the identity and concentration of organic pollutants in residential air. An evaluation was completed in FY 1983 of the toxicological significance of seventeen of the compounds present during monitoring. Additional monitoring efforts to define highly volatile organic chemicals, that may be of more toxicological significance will be completed in FY 1984. Efforts to identify the sources of the most toxicologically significant of the organic chemicals will be completed in FY 1984. Hazard evaluation of organic chemicals and recommendations for remedial strategies will be completed in FY 1985.

- Asbestos in Products. Inhalation of microscopic fibrous particles of asbestos is recognized as a cause of lung cancer in humans. The Commission re-established a testing facility, and during FY 1983 tested products for emission of asbestos fiber. The Commission established and received the report of a Chronic Hazard Advisory Panel on asbestos during FY 1983. In FY 1984 the Commission will, if warranted, begin rulemaking on certain products which could expose consumers to hazardous asbestos fibers.

- Children's Chemical Hazards. In FY 1984, the Commission will continue efforts on children's chemical hazards--school lab chemicals and children's exposure to carcinogens--as priority activities.

  - Children's Chemical Hazards. Children enrolled in some school laboratory classes may be exposed to toxic chemicals for which the hazards and unsafe uses may not be known even by the instructor. For example, formaldehyde, a carcinogen, is still used in chemistry classes. The Commission staff developed a program to inform teachers about chronic adverse health effects of school laboratory chemicals, and to advise teachers regarding less hazardous substitute chemicals and to use precautions necessary to minimize classroom exposure. During FY 1982, the Chemical Hazards Program completed the technical evaluation and guidance portion of the effort to inform teachers of the health hazards of school lab chemicals. During FY 1983, this information was disseminated by the Council of State Science Supervisers. During FY 1984, the classroom teachers' evaluations of the material will be reviewed to determine if revisions are necessary.

  - Children's Exposure to Carcinogens. During FY 1984, the Commission will determine the success of FY 1983 efforts to encourage the industry to voluntarily reduce/remove two identified carcinogens from children's products:

-- Nitrosoamines. Testing during FY 1983 demonstrated that these potent carcinogenic substances can be ingested by a child sucking on pacifiers made of latex rubber. The Commission investigated the exposure to these substances and the potential risk involved, and has worked with the industry to reduce or eliminate nitrosoamine contamination of children's products. During FY 1984 the Commission will decide whether voluntary action has sufficiently reduced the hazard and will convene a Chronic Hazard Advisory Panel, if warranted.

-- Plasticizers. An estimated 9-22 million pounds of the plasticizer, di(2-ethylhexyl)phthalate (DEHP), is used annually in 130 million children's products. DEHP has been shown to be carcinogenic to laboratory animals. Testing completed in FY 1983 demonstrated that children are exposed to DEHP through oral and skin contact with plastic articles (for example, teething rings) containing DEHP. Based on the results of the exposure testing, an in-depth toxicity assessment and risk assessment was completed in FY 1983, the Commission may convene a Chronic Hazard Advisory Panel (CHAP) in FY 1984 to evaluate the carcinogenicity of DEHP. Based on the CHAP report, the Commission will decide whether to issue an ANPR.

o Interagency Support. The CPSC coordinates with other Federal agencies to share information, expertise and facilities as well as to avoid duplication and to seek consistent Federal approaches to common problems. In 1983, the Commission shared information on adverse health effects and consumer use with EPA for over 70 new chemicals and for over 50 chemicals already in production. It shared its expertise with FDA on nitrosoamines in pacifiers and on tamper proof packaging (Tylenol) and with the National Toxicology Program, which tests chemicals which may be used in consumer products. In 1984, the

Commission will work with other agencies on three CPSC 1984 priority projects: chlorocarbons, fire toxicity and indoor air quality. The Commission is also involved with other Federal agencies under the direction of the Office of Science and Technology Policy to complete development of consistent principles for the identification and evaluation of cancer causing substances.

B. Proposed FY 1985 Activities

- Poison Prevention.
  - Dual Purpose Packaging. In FY 1985, the Commission staff will evaluate the results of the consumer survey of ingestion incidents started in FY 1984. Recommendations for further study, if necessary, will be developed.
  - Special Packaging. In FY 1985, CPSC will complete action on special packaging requirements for petroleum distillates and will develop recommendations for topical drugs.
  - Testing. The Commission will compete verification tests for revisions to the PPPA protocol. Appropriate action for specific revisions to the protocol will be completed.
  - Exemptions. The Commission will continue to process industry requests for exemptions from special packaging regulations.
- Chlorocarbons. Preliminary results of long term animal tests of dichloromethane (used as a paint remover and solvent) and perchloroethylene (widely used in dry cleaning) indicate that these chemicals may cause cancer and other adverse health effects. Both chemicals are widely used by consumers. Based on test results of FY 1983 and FY 1984, the Commission will conduct toxicity and exposure assessments to determine the risk posed to consumers, and may in FY 1984 convene a Chronic Hazard Advisory Panel to assist in evaluating the hazard. This project is a Commission priority in FY 1984 and FY 1985.

- Emerging Chemical Hazards. In FY 1985, the Commission will maintain and update its computerized data system for tracking chemicals (STIC) by continuing to monitor major sources of toxicity data for chronic chemical hazards in consumer products.

- Dyes and Finishes. The Commission will continue to assess the toxicity and bioavailability of dyes and flame retardants which may be hazardous to consumers.

- Indoor Air Quality. The Commission will continue to emphasize the characterization of pollutant emissions from combustion appliances and the development of voluntary standards to reduce emissions from those which may pose a hazard to consumers in the home.

    - Combustion Products. The Commission will determine the extent of the hazard presented by exposure to toxic combustion products emitted from various fuel-fired appliances, and will work with industry to develop remedial strategies, as appropriate. The success of voluntary industry action on unvented gas space heaters and kerosene heaters will be assessed in FY 1985. Hazard analyses for gas stoves, coal and wood stoves should be completed in FY 1985.

    - Asbestos. The Commission will prepare a report on consumer exposure to asbestos from permanent home fixtures such as furnaces, boiler cement and duct work. The report will include information for consumers on the safe handling of these products.

    - Organic Pollutants. Major hazardous organic pollutants and their consumer product sources will be identified from the 40 home monitoring study data. Population exposure and risk will be estimated and cost effective remedial strategies reviewed. This project effort will be completed in FY 1985.

- Carcinogens in Children's Products. If it is recommended that Chronic Hazard Advisory Panel be convened, the Panel will complete its review in FY 1984 of phthalate carcinogenicity, and the Commission will undertake appropriate remedial strategies, in FY 1984 and FY 1985 as required. If voluntary industry action has not reduced the identifiable hazards from nitrosoamines in rubber children's products, an advisory panel in FY 1984 will review selected nitrosoamines as a preliminary step toward possible regulatory action. In FY 1985, regulatory action would be implemented.

- Strong Sensitizers. Based on the hazard assessment and evaluation to be completed in FY 1984, the Commission may identify additional chemicals which are strong sensitizers, and initiate appropriate action, re: consumer products containing these chemicals.

- Interagency Support. The Commission is expected to continue its cooperative activities with the Federal agencies in research planning, chemical testing, facilities sharing, coordinated regulatory development and risk assessments.

II. Health Sciences Support

A. FY 1983 and FY 1984 Activities

- Lab Facilities. The Commission continues to share laboratory facilities, equipment and expertise with the Food and Drug Administration.

- Toxicity Support. In FY 1983, Health Sciences collected and evaluated toxicity data on several hundred chemicals and chemical classes for a number of the Commission's hazard programs. Health Sciences collected poison information from several data bases and administered the CPSC contract for pathology services. Toxicity data collection and evaluation will continue at approximately the same level for FY 1984, with attention being focused on volatile organics in indoor air, combustion products, chlorocarbons, strong sensitizers, chlorinated hydrocarbons, fire retardants, dyes, petroleum distillates, topical drugs, and various chemicals in household products reviewed by the Toxicological Advisory Board.

- Short-Term Testing. In FY 1983, the Directorate for Health Sciences conducted tests of chemicals in consumer products for mutagenicity and carcinogenicity. Testing results were used as a basis for further testing by the National Toxicology Program. Due to staff constraints, this project will be substantially reduced in scope in FY 1984.

- Exposure/Risk Assessment. In FY 1983, Health Sciences analyzed human exposure to chemicals such as dyes, nitrosoamines, phthalates and formaldehyde from pressed wood products. In addition, by use of computerized models for risk estimation, the Commission was able to perform risk assessments for consumer exposure to chemicals such as nitrosoamines, formaldehyde, and phthalates. In FY 1984, such assessments are planned for methylene chloride, perchloroethylene and formaldehyde in pressed wood products, and for other chemicals as needed.

- Biological, Medical and Toxicological Support. In FY 1983, Health Sciences provided extensive support services to various Commission hazard programs and compliance activities. In FY 1984, the Directorate will continue to provide these services.

- Mast Cell Test. In FY 1983, Health Sciences developed preliminary methodology needed to evaluate the use of cell cultures for initial screening for eye irritation testing. Due to staff constraints, this project will be reduced in scope in FY 1984.

B. Proposed FY 1985 Activities

- Health Sciences Support. The Directorate for Health Sciences will continue to provide biological, medical and toxicological support to Commission hazard programs and compliance efforts as requested.

- Exposure/Risk Assessment. Exposure and risk assessments will continue to be performed for potentially hazardous chemicals found in consumer products. Such assessments may involve hazardous dyes, chlorinated hydrocarbons and various indoor air pollutants.

- Toxicity Support. Collection and evaluation of toxicity data on suspected chemical hazards will continue. An estimated 200 chemicals will be reviewed.

- Laboratory Equipment. To maintain a state-of-the-art capability in the Health Sciences Laboratory, obsolete laboratory equipment will be replaced or upgraded, thereby enabling in-house laboratory analyses to be carried out in an effective, accurate and cost-effective manner.

- Laboratory Facilities. CPSC will continue to share facilities, equipment and expertise with FDA.

COUNCIL ON ENVIRONMENTAL QUALITY

722 Jackson Place NW
Washington, D.C. 20006

Locator: 202-395-5700
Information: 202-395-5770

Organization.................... page 33
Statutory Authorities.......... page 34
Toxics-Related Activities...... page 36

The Council on Environmental Quality (CEQ) is the policy advisory body for environmental matters in the Executive Office of the President. Created by the National Environmental Policy Act of 1969 (NEPA), its principal responsibilities are to oversee the implementation of that Act and to develop and advise the President on national policies and programs affecting environmental quality. Additional responsibilities were provided by the Environmental Quality Improvement Act of 1970, Executive Order 11514, as amended by Executive Order 11991, and reorganization Plan No. 1 of 1977.

The Council on Environmental Quality's general charge includes:

- Developing and recommending national policies which foster and promote improvement of environmental quality, including review and assessment of the effectiveness of existing and proposed Federal facilities, program policies, and activities which affect environmental quality; development of the President's environmental message to Congress; and assisting in development of the President's environmental legislation programs.
- Assisting Federal agencies in coordinating programs and activities which affect, protect, and improve environmental quality. This includes promulgating and maintaining regulations implementing the procedural provisions of NEPA and the referral process under section 309 of the Clean Air Act, overseeing the NEPA

process, developing guidelines for evaluating environmental impacts of Federal actions, and developing and promoting means to prevent or reduce adverse effects of such actions.

- Gathering and analyzing information concerning conditions and trends in the quality of the environment, developing special studies and analyses on environmental quality and health, and assisting the President in the preparation of the annual environmental quality report to the Congress.

The Council's specific statutory responsibilities include:

- Issuing regulations to implement the procedural provisions of NEPA, including regulations for the preparation of environmental impact statements (EIS) for major Federal actions which significantly affect the quality of the human environment.
- Resolving conflicts which are referred to the Council by agencies under Section 102(2) of NEPA and Section 309 of the Clean Air Act.
- Preparing for transmittal by the President to the Congress an annual report setting forth conditions and trends in environmental quality.

CEQ addresses a wide variety of environmental policy issues, including those pertaining to evaluation of the health effects of exposure to toxic substances, and program and/or regulatory strategies for their control. CEQ has a long and active involvement in the toxic substances and environmental health fields. CEQ prepared the first Toxic Substances Control Act (TSCA) legislation proposed to Congress by the President in 1970 and participated in events leading to the passage of TSCA in 1976. CEQ has been involved in the implementation of TSCA, participating in the development and review of various program and budget issues. CEQ cochairs (with EPA) the Interagency Toxic Substances Data Committee, a permanent interagency committee formed pursuant to Section 10(b) of the Toxic Substances Control Act and other legislative and executive mandates. The Data Committee is charged with the responsibility of developing an integrated data network to support Government in toxics research and regulation. The Council is a statutory member of the Interagency Testing Committee formed pursuant to Section 4 of TSCA and participates in other interagency committees addressing toxics research and regulation. The Council also has been active in promoting Federal support for the development and use of integrated pest management and in analyzing the economic benefits of toxic substances regulations.

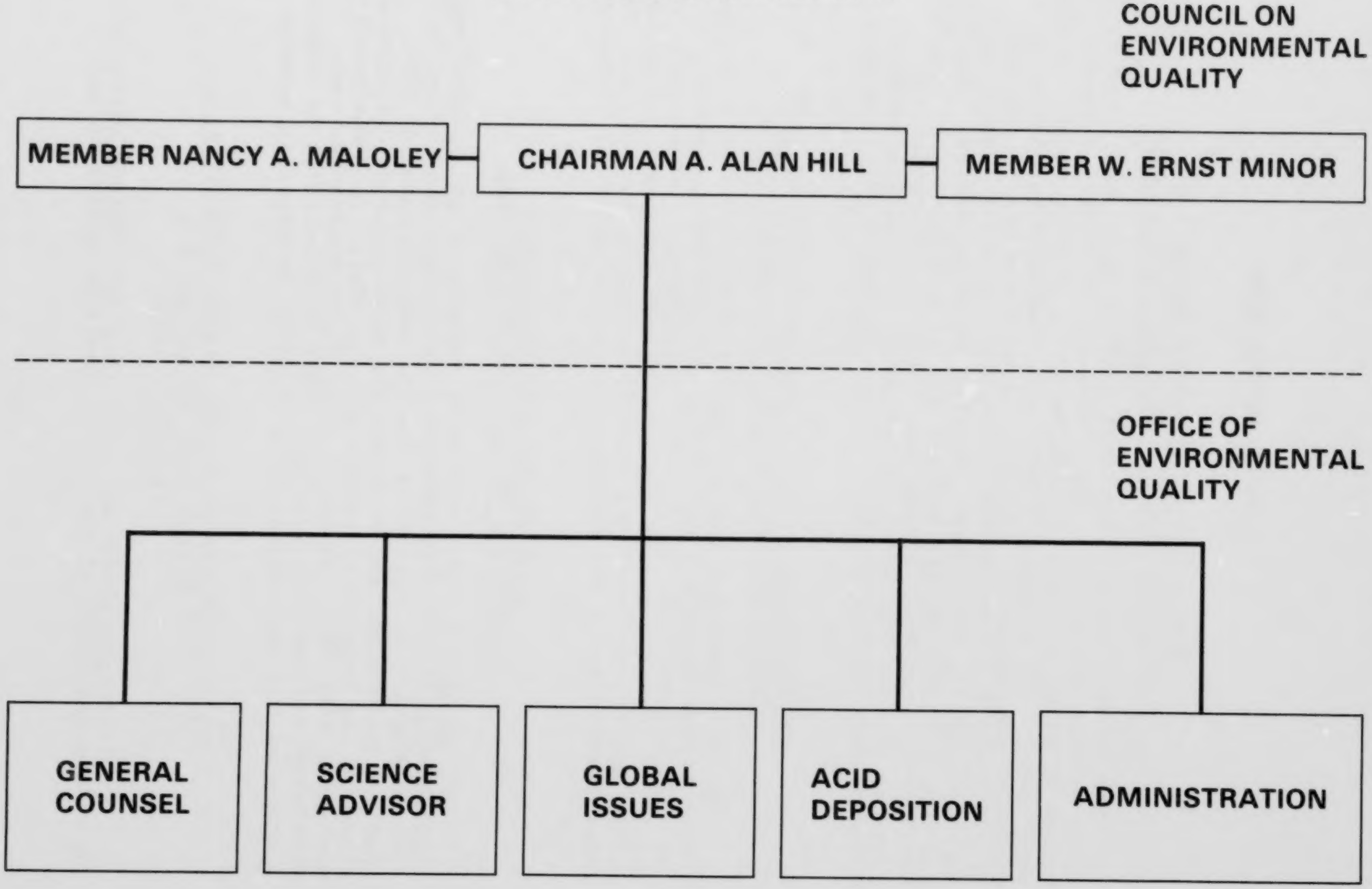
The Council on Environmental Quality operates on a policy level to assist Federal agencies in program development and implementation and to provide environmental advice to the President. The Council does not issue "toxics regulations." Therefore, a regulatory development section is not included for this agency.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Name	Title	Phone	Area of Focus
W. Ernst Minor	Council Member	202-395-4506	Environmental health and toxic substances
Dinah Bear	General Counsel	202-395-5754	Environmental impact statements

COUNCIL ON ENVIRONMENTAL QUALITY/OFFICE OF ENVIRONMENTAL QUALITY

ORGANIZATION CHART



COUNCIL ON
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QUALITY

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MEMBER W. ERNST MINOR

OFFICE OF
ENVIRONMENTAL
QUALITY

GENERAL COUNSEL

SCIENCE ADVISOR

GLOBAL ISSUES

ACID DEPOSITION

ADMINISTRATION

NOVEMBER 29, 1982

STATUTORY AUTHORITIES

National Environmental Policy Act
Public Law 91-190 42 U.S.C. §§4341-4347

The Council on Environmental Quality was established in 1970 under Section 202 of this Act. NEPA establishes a national policy of using all practicable means to prevent damage to the environment. It charges Federal agencies with the duties of analyzing the potential impact of a proposed action and its alternatives and considering these impacts and the goals set forth in NEPA in the course of their decision making. The duties and functions of CEQ are spelled out in Section 204 of the Act. Among other responsibilities, the Council must review and appraise the various programs and activities of the Federal Government to determine their consistency with NEPA's goals.

Environmental Quality Improvement Act of 1970
Public Law 91-224 42 U.S.C. §§4371-4374

The Environmental Quality Improvement Act of 1970 created an Office of Environmental Quality to provide staff support to CEQ. It brought more funding and responsibilities to CEQ. It specified that CEQ should appraise Federal programs and policies, review monitoring, evaluate the effects of technology, and assist Federal agencies in the development of environmental standards.

Toxic Substances Control Act
Public Law 94-469 15 U.S.C. §2601

CEQ is one of eight statutory members of the Interagency Testing Committee. This Committee was established under Section 4(e) of the Act to recommend (to the Administrator of EPA) chemical substances and mixtures for priority consideration when promulgating regulations under section 4(a). In addition, CEQ cochairs, with EPA, the Interagency Toxic Substances Data Committee and has been directed under Section 25(b) to coordinate a study on the development of a chemical information network.

Health Services Research, Health Statistics, and Health Care Technology Act
42 U.S.C. §242

CEQ's responsibilities under this Act include participation in an ongoing study of the health costs of pollution and assistance in the establishment of guidelines for the collection of health information and statistics in order to improve coordination of environmental and health studies.

Executive Order 11514 (March 5, 1970) as amended by Executive Order 11991 (May 24, 1977), and Reorganization Plan No. 1 of 1977

This Order and Plan empowers the Council to recommend to the President and to Federal agencies priorities in environmental programs. It gives the Council responsibility for advising and assisting the President and Federal agencies in achieving international cooperation for dealing with environmental problems, under the foreign policy guidance of the Secretary of State. It also authorizes the Council to issue regulations binding on all Federal agencies to implement the procedural provisions of the National Environmental Policy Act.

Environmental Effects Abroad of Major Federal Actions, January 5, 1979
Executive Order 12114

This Order requires that environmental review procedures be established for major international Federal actions, including those involving the export of a product or involving a facility whose products, emissions, or effluents are prohibited or regulated because their toxic effects on the environment create a serious public health risk.

TOXICS-RELATED ACTIVITIES

Program Description

The Council's toxics program is policy oriented. CEQ conducts studies on an ad hoc basis, develops programs for interagency coordination and makes recommendations for executive action.

DEPARTMENT OF AGRICULTURE

14th Street and Independence Avenue SW.
Washington, D.C. 20250

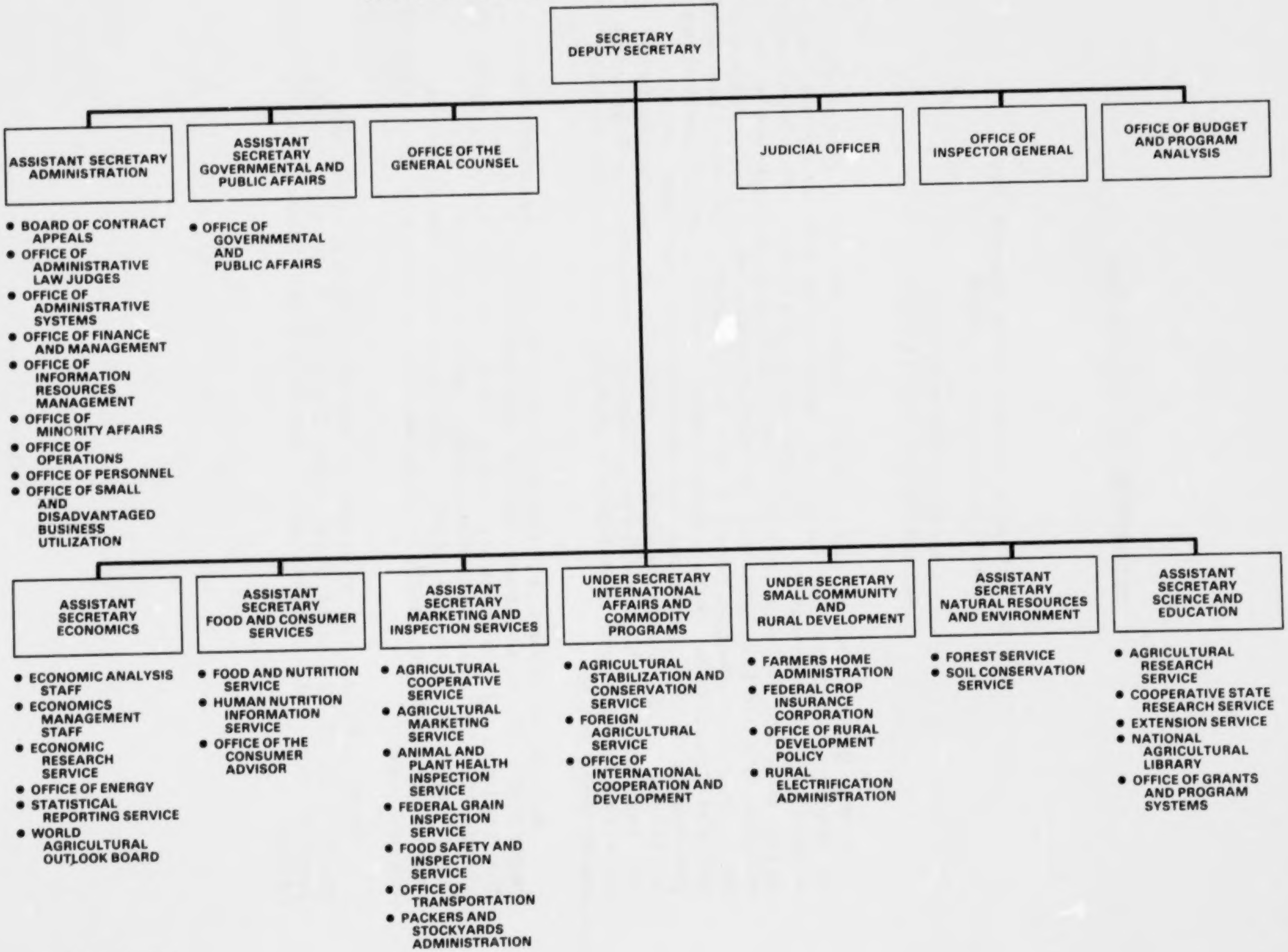
Locator: 202-655-4000
Information: 202-447-5247

The Department of Agriculture (USDA) serves all Americans. It works to improve and maintain farm income and to develop and expand markets abroad for agricultural products. The Department helps to curb poverty, hunger, and malnutrition. It works to enhance the environment and to maintain our production capacity by helping landowners protect the soil, water, forests, and other natural resources. Rural development, credit, and conservation programs are key resources for carrying out national growth policies. USDA research findings directly or indirectly benefit all Americans. The Department, through inspection and grading services, safeguards and assures standards of quality in the daily food supply.

An act of Congress, approved May 15, 1862, created the Department of Agriculture, which was administered by a Commissioner of Agriculture until 1889. On February 9, 1889, the powers and duties of the Department were enlarged. The Department was made the eighth executive department in the Federal Government, and the Commissioner became the Secretary of Agriculture.

This publication focuses on the responsibilities and activities of the Food Safety and Inspection Service (FSIS) located within the Department's Marketing and Inspection Services Office.

UNITED STATES DEPARTMENT OF AGRICULTURE



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  - ASSISTANT SECRETARY ADMINISTRATION
    - BOARD OF CONTRACT APPEALS
    - OFFICE OF ADMINISTRATIVE LAW JUDGES
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  - ASSISTANT SECRETARY ECONOMICS
    - ECONOMIC ANALYSIS STAFF
    - ECONOMICS MANAGEMENT STAFF
    - ECONOMIC RESEARCH SERVICE
    - OFFICE OF ENERGY
    - STATISTICAL REPORTING SERVICE
    - WORLD AGRICULTURAL OUTLOOK BOARD
  - ASSISTANT SECRETARY FOOD AND CONSUMER SERVICES
    - FOOD AND NUTRITION SERVICE
    - HUMAN NUTRITION INFORMATION SERVICE
    - OFFICE OF THE CONSUMER ADVISOR
  - ASSISTANT SECRETARY MARKETING AND INSPECTION SERVICES
    - AGRICULTURAL COOPERATIVE SERVICE
    - AGRICULTURAL MARKETING SERVICE
    - ANIMAL AND PLANT HEALTH INSPECTION SERVICE
    - FEDERAL GRAIN INSPECTION SERVICE
    - FOOD SAFETY AND INSPECTION SERVICE
    - OFFICE OF TRANSPORTATION
    - PACKERS AND STOCKYARDS ADMINISTRATION
  - UNDER SECRETARY INTERNATIONAL AFFAIRS AND COMMODITY PROGRAMS
    - AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE
    - FOREIGN AGRICULTURAL SERVICE
    - OFFICE OF INTERNATIONAL COOPERATION AND DEVELOPMENT
  - UNDER SECRETARY SMALL COMMUNITY AND RURAL DEVELOPMENT
    - FARMERS HOME ADMINISTRATION
    - FEDERAL CROP INSURANCE CORPORATION
    - OFFICE OF RURAL DEVELOPMENT POLICY
    - RURAL ELECTRIFICATION ADMINISTRATION
  - ASSISTANT SECRETARY NATURAL RESOURCES AND ENVIRONMENT
    - FOREST SERVICE
    - SOIL CONSERVATION SERVICE
  - ASSISTANT SECRETARY SCIENCE AND EDUCATION
    - AGRICULTURAL RESEARCH SERVICE
    - COOPERATIVE STATE RESEARCH SERVICE
    - EXTENSION SERVICE
    - NATIONAL AGRICULTURAL LIBRARY
    - OFFICE OF GRANTS AND PROGRAM SYSTEMS

OCTOBER 4, 1982

THE FOOD SAFETY AND INSPECTION SERVICE

U. S. Department of Agriculture
14th and Independence Avenue SW.
Washington, D.C. 20250

Locator: 202-447-6617
Information: 202-447-7943

Organization..........................page 41
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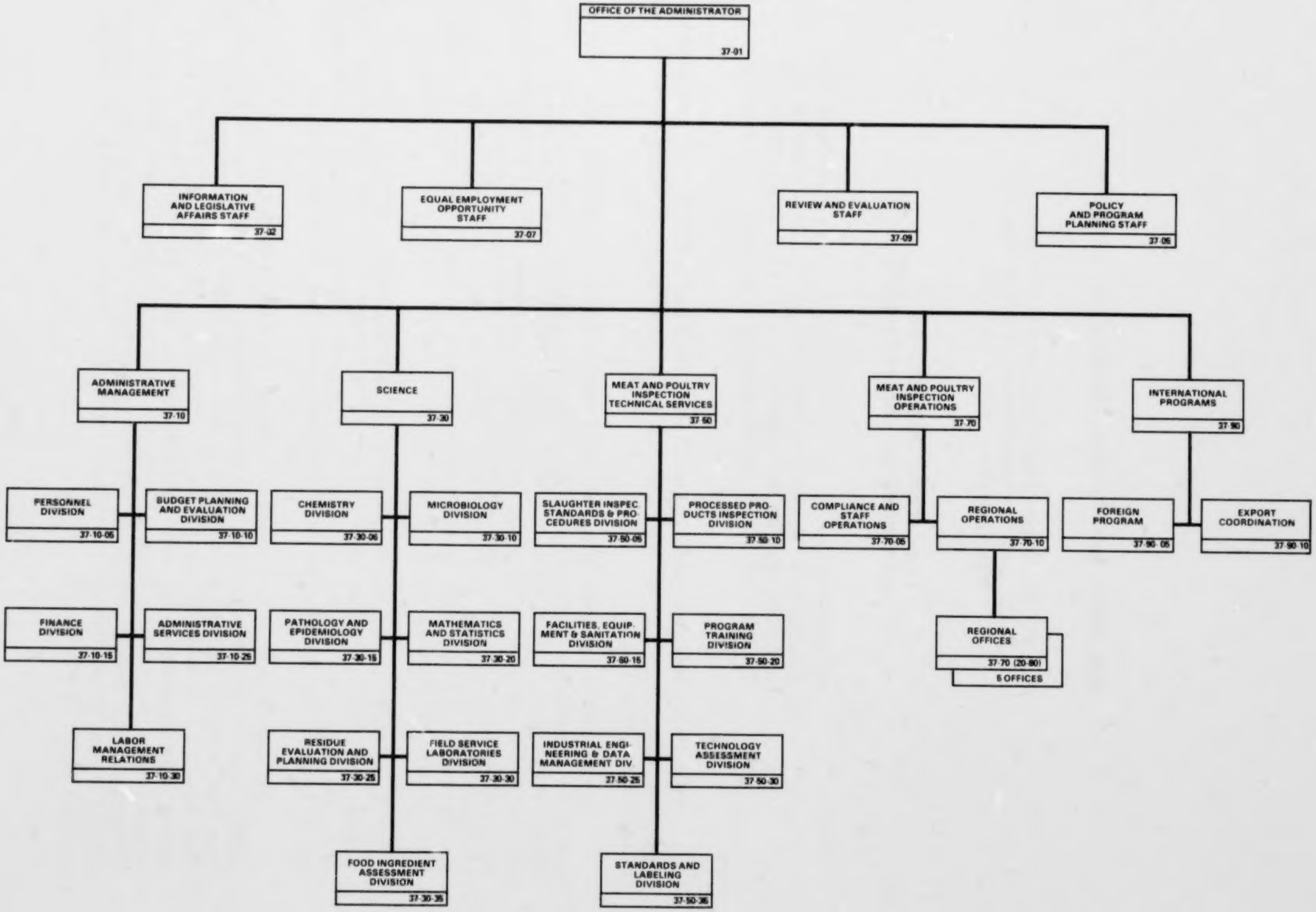
The Food Safety and Inspection Service (FSIS) is responsible for inspection of meat and poultry for safety, wholesomeness, and accurate labeling.

FSIS administers the Federal Meat Inspection Act and the Poultry Products Inspection Act, which provide for uniform Federal-State inspection of all meat and poultry products. Inspection regulations require prior approval of the construction and equipment of plants operating in interstate commerce; inspection of birds and animals before, during, and after slaughter; continuous inspection of all processing operations; and prior approval of labels for meat and poultry products.

The FSIS inspection program also includes activities to guard against disease and residues in domestic and imported meat and poultry products, and monitoring activities in foreign plants handling these products for import into the United States.

In addition, FSIS participates in the regulation of toxics under two separate statutory authorities. First, FSIS may issue its own regulations as provided by both the Meat Inspection and the Poultry Products Inspection Acts for any toxic substances which may threaten to contaminate meat and poultry food supplies. Second, under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Food and Drug Administration (FDA) also regulates toxic substances which may be found in foods (as well as drugs or cosmetic products).

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE


OFFICE OF THE ADMINISTRATOR
37-01
INFORMATION AND LEGISLATIVE AFFAIRS STAFF
37-02
EQUAL EMPLOYMENT OPPORTUNITY STAFF
37-07
REVIEW AND EVALUATION STAFF
37-09
POLICY AND PROGRAM PLANNING STAFF
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LABOR MANAGEMENT RELATIONS
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SCIENCE
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CHEMISTRY DIVISION
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MICROBIOLOGY DIVISION
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PATHOLOGY AND EPIDEMIOLOGY DIVISION
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MATHEMATICS AND STATISTICS DIVISION
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RESIDUE EVALUATION AND PLANNING DIVISION
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FIELD SERVICE LABORATORIES DIVISION
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MEAT AND POULTRY INSPECTION TECHNICAL SERVICES
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SLAUGHTER INSPEC. STANDARDS & PROCEDURES DIVISION
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FACILITIES, EQUIPMENT & SANITATION DIVISION
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PROGRAM TRAINING DIVISION
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INDUSTRIAL ENGINEERING & DATA MANAGEMENT DIV.
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TECHNOLOGY ASSESSMENT DIVISION
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MEAT AND POULTRY INSPECTION OPERATIONS
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COMPLIANCE AND STAFF OPERATIONS
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REGIONAL OPERATIONS
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5 OFFICES
INTERNATIONAL PROGRAMS
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FOREIGN PROGRAM
37-90-05
EXPORT COORDINATION
37-90-10

The mission of the Food Safety and Inspection Service is to provide assurance to the consumer that foods are safe, wholesome, and nutritious, and that they are informatively and honestly labeled.

ORGANIZATION*

OFFICE OF THE ADMINISTRATOR

Maintains management control over the following activities delegated to FSIS by the Secretary of Agriculture:

Inspection programs for meat and poultry;
Processing and distribution of various food products; and
Transportation and sale of foods determined unsafe.

SCIENCE PROGRAM (SCI)

- o Works in conjunction with the Office of the Administrator to formulate FSIS scientific and laboratory policies and to coordinate research projects.
- o Operates the FSIS regulatory field service laboratories and maintains liaison with other laboratories around the world.
- o Conducts a program of scientific data collection and review.
- o Conducts the food-borne hazard reporting system for the detection of human diseases stemming from bacteria in meat and poultry and the regulation of direct and indirect additives in those foods.

Chemistry Division (SCI)

- o Develops analytical methods and approves those that are suitable for supporting a regulatory program.
- o Conducts special studies for FSIS where necessary and performs comparison studies with Federal and commercial laboratories.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Maintains a quality assurance program to ensure the validity of analytical results.

Microbiology Division (SCI)

- Conducts a general microbiology program to identify pathogens and toxins in support of meat and poultry inspection (MPI) field programs.
- Analyzes canned foods and determines the presence of extraneous material in food products in support of MPI field programs.
- Develops new methods for detecting antibiotic residues.
- Maintains a quality assurance program to ensure the validity of results.

Pathology and Epidemiology Division (SCI)

- Assists MPI with the development of criteria used in ante mortem and post mortem inspections of livestock and poultry.
- Operates a national diagnostic pathology program and a food-borne hazard reporting center to investigate potential risks of unsafe meats and poultry to human health.
- Studies the application of field tests in pathology and parasitology.

Residue, Evaluation, and Surveillance Division (SCI)

- Conducts monitoring and surveillance programs to determine the extent of drug, pesticide, antibiotic, and environmental residues in food of animal origin.
- Assists in the evaluation of cooperative residue programs performed by industry.
- Conducts toxicological studies of substances found in meat and poultry.

Food Ingredient Assessment Division (SCI)

- Coordinates the establishment of FSIS nutritional policies and recommends research.
- Approves use of food additives in meat and poultry products.
- Determines safety of compounds and packages used by industry.

Field Service Laboratories Division (SCI)

- Analyze meat and poultry and their products to determine the presence of environmental and drug contaminants, naturally occurring toxins, poisons, and economic adulteration using the disciplines of chemistry, microbiology, and pathology.
- Supervises contract laboratories that analyze meat and poultry and their products for economic adulteration and for chlorinated hydrocarbon pesticides.

MEAT AND POULTRY INSPECTION (MPI)

- Ensures the wholesomeness of meat and poultry products in interstate and foreign commerce by in-plant inspection of all livestock and poultry as well as the reinspection of processed meat and poultry products.
- Conducts field tests and inspections of livestock, poultry, and derived products.
- Controls and disposes of condemned and inedible foods.
- Monitors processing facilities, and reviews the inspection system of countries exporting food to the United States.
- Monitors and evaluates State meat and poultry inspection programs.

Regional Operations (MPI)

- Inspects meat and poultry products during processing.

- Checks the accuracy of label information and monitors plants, other facilities, and individuals for compliance with legal orders.
- Inspects meat and poultry entering or leaving the United States.

Regional Offices (MPI)

- Plans and coordinates Regional Operations programs for inspection, control of condemned products, and a variety of other activities relating to facilities and processing.
- Reviews State inspection programs and coordinates activities between the States and the Federal Government.
- Grants and suspends inspection privileges under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Compliance Division (MPI)

- Supervises FSIS monitoring and enforcement programs.
- Work with other FSIS programs to formulate new policies and programs.
- Coordinates the development of FSIS regulations and takes action to ensure regulatory compliance.
- Administers enforcement activities, advises the Administrator on matters of regulatory compliance, and maintains liaison with other enforcement groups.
- Initiates actions to withdraw services and conducts debarment procedures.

TECHNICAL SERVICES (TS)

- Analyzes agricultural practices and scientific advances for their effect on food safety and public health.
- Develops procedures for inspecting livestock, poultry, and their processed products and coordinates the

establishment of regulatory criteria concerning the disposition of carcasses.

- o Develops the Agency's labeling policy and standards for meat and poultry.
- o Develops requirements for facilities, equipment, and sanitation and approves new construction and equipment for meat and poultry plants.
- o Prepares environmental and economic impact statements for regulations issued by the Agency.

POLICY AND PROGRAM PLANNING (PPP)

Regulations Office (PPP)

- o Publishes FSIS regulations, instructions, and notices.
- o Reviews regulations for adequacy, clarity, and compliance with Agency requirements.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL*

Division/Office	Phone	Room
Office of the Administrator	202-447-7025	332-E
Science Program	202-447-2326	402-A
Chemistry Division	202-447-7623	404-A
Microbiology Division	202-447-4212	410-A
Pathology and Epidemiology Div.	301-344-2460	101-318-C Beltsville, Md.
Residue Evaluation and Surveillance Division	202-447-2807	602-A
Field Service Laboratories Div.	202-447-4954	412-A
Food Ingredient Assessment Div.	202-447-7680	510-A

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*FTS numbers are the same.

Policy and Program Planning	202-447-6525	327-E
Regulations Office	202-447-3317	2940-S
Meat and Poultry Inspection	202-447-8803	344-E
Regional Operations	202-447-3697	4860-S
Technical Services	202-447-2709	350-E

REGIONAL AND FIELD OFFICES (MPI)

Western Regional Office	620 Central Ave. Bldg. 2C Alameda, CA 94501	415-273-7402
Northeastern Regional Office	1421 Cherry St. 7th Floor Philadelphia, PA 19102	215-597-4217
Southeastern Regional Office	1718 Peachtree St., NW. Room 216 Atlanta, GA 30309	404-881-3911
Southwestern Regional Office	1100 Commerce St. Room 5F41 Dallas, TX 75242	214-767-9116
Northcentral Regional Office	607 E. Second St Des Moines, IA 50316	515-284-4042

STATUTORY AUTHORITIES

Federal Meat Inspection Act
Public Law 90-201 21 U.S.C. §601 et seq.

The Federal Meat Inspection Act is the result of a 1967 congressional revision (the Wholesome Meat Act of 1967) of the original Meat Inspection Act of 1907. The purposes of the Act are to provide safe and wholesome meat and meat products and to ensure uniform inspection, labeling, and packaging of meats.

Key Sections of Act--Toxics Focus

sec. 1(m)	Gives a detailed definition of the word "adulterated" by including any carcass, meat, or meat product that is found to include poisonous or deleterious substances, including pesticides, chemicals, additives, or colorings that are found unfit for human food.
sec. 1(m) (2)(c)	Prohibits the use of any food additive determined unsafe under the Food, Drug, and Cosmetic Act (sec. 409).
sec. 2	Expresses the concern of Congress to assure that meat and meat products are wholesome, properly marked, labeled, and packaged.
sec. 3	Requires the Secretary to provide rules and regulations for animal inspection, and segregation for diseased animals.
sec. 4	Requires a post mortem inspection of all animals slaughtered to determine possible adulteration.
sec. 10	Prohibits any person, firm, or corporation from selling adulterated or misbranded meat and meat products. Also, this section prohibits the handling of meat and meat products in a way that causes adulteration or misbranding.
sec. 20	Requires importation of meat only from countries maintaining inspection systems equivalent to United States systems. The section also requires the reinspection of products at the port of entry.

sec. 402	Requires the detention and destruction of adulterated products found moving in commerce.
sec. 409	Requires that tolerances established for various substances be coordinated with those established by the Food and Drug Administration under FFDCA section 408.

Regulatory Options Available Under Statute

- Prescribe and implement terms and conditions for destruction
- Refuse to inspect and pass or clear
- Refuse to stamp, mark, tag, or label
- Notify the Governor of the State
- Refuse to provide or withdraw inspection services
- Detain
- Proceed against, seize, and condemn
- Determine fine or imprisonment or both
- Issue injunctions

The Poultry Products Inspection Act
Public Law 90-492 21 U.S.C. §451 et seq.

The Poultry Products Inspection Act was first passed in 1957, then amended in 1962 and 1968. The Act provides for the uniform inspection of poultry and poultry products and for the regulation of poultry processing and distribution practices. The principal purpose of the Act is to ensure that poultry and poultry products are wholesome, properly marked, labeled, and packaged.

Key Sections of Act-Toxics Focus

sec. 4(g)	Gives a detailed definition of the term "adulterated." "Adulteration" applies to any poultry carcass or poultry product that is

	found to contain added poisonous or deleterious substances, including pesticides, chemicals, additives, or colorings that are found unfit for human food within the meanings of sections 408 and 409 of the FFDCA.
sec. 1(y)	Defines the terms "pesticide chemical", "color additive", and "raw agricultural commodity" as having the same meanings as in FFDCA.
sec. 6(a)	Requires an ante mortem inspection of all poultry suspected of adulteration at official establishments or facilities subject to inspection under this Act.
sec. 6(b)	Requires a post mortem inspection of all birds processed and a quarantine and segregation if the birds are found unsafe for human food.
sec. 6(c)	Requires the condemnation and destruction of all adulterated birds.
sec. 9(a)(4)	Prohibits the sale, transport, or offer for sale of any adulterated or misbranded poultry products.
sec. 14	Regulates the condition under which poultry products for human food will be stored or handled to prevent adulteration or misbranding.
sec. 17	Prohibits the importation of slaughtered poultry or poultry products unless they are healthful, wholesome, fit for human food, and not adulterated. They must contain no dye, chemical, preservative, or ingredient unfit for human consumption.

Regulatory Options Available Under Statute

- Condemn and destroy
- Refuse to render, provide, or withdraw inspection service
- Quarantine, segregate, and reinspect
- Withhold use

- Determine fine or imprisonment or both
- Prescribe conditions for storage and handling
- Destroy and prescribe terms and conditions for destruction
- Detain
- Proceed against, seize, and condemn
- Issue injunctions.

The Federal Food, Drug, and Cosmetic Act
Public Law 69 21 U.S.C. §§301-392

The purpose of FFDCA is to safeguard public health by prohibiting the introduction into interstate commerce of any food, drug, or cosmetic that is adulterated or misbranded and to regulate additives and toxins in foods. FSIS is given statutory authority under three sections of the Act.

Key Sections of Act--Toxics Focus

sec. 408	Authorizes the establishment of tolerances for pesticide chemical residues in food in order to protect public health.
sec. 409	Deems a food additive unsafe unless it is proven safe.
sec. 512	Following the Drug Animal Amendments of 1968, a separate class of substances known as "new animal drugs" was established with FFDCA. Such substances are regulated when residues in foods exceed the tolerance levels established under this section.

Regulatory Options Available Under Statute

- Ban
- Set tolerances
- Deem products to be misbranded

- Establish standards or conditions
- Require registration or certification

REGULATORY DEVELOPMENT

REGULATORY PROCESS

Regulatory development at FSIS is a three-part process which begins with the placement of a regulatory initiative on the FSIS Work Plan. (This is explained in greater detail in the steps below.) Both the Office of Primary Interest and the Regulations Coordination Division play a central role in this process. Also, the Meat and Poultry Inspection and Science Programs provide special assistance and information regarding decisions to regulate or rule against harmful adulterants in meat and poultry products.

1. The Office of Primary Interest (which may include any Division Office within FSIS) begins the regulatory process by entering an initiative onto the FSIS Work Plan. Once on the Work Plan, the initiative may be published in the Federal Register.

2. Reviews and studies are conducted on all available information. Special assistance and information may also be provided by the Meat and Poultry Inspection and Science Programs.

3. When the decision is found to be significant or not significant, an Impact Analysis is prepared.

4. The Office of Primary Interest prepares the rule or regulation (Docket) and submits it to the Regulations Coordination Division for movement through the final review process. This process involves the Office of Primary Interest, the Deputy Administrators, and the General Counsel. Also at this time, the Docket is submitted to Policy and Program Planning for the development of a public participation plan as appropriate.

5. The approved Docket, along with a proposed public participation plan and comments, are presented to the Administrator for final approval.

6. The proposed or Final Standard is published in the Federal Register.

EXISTING REGULATIONS

Federal Meat Inspection Act	9 CFR 301-335
Poultry Products Inspection Act	9 CFR 301-329, 381
Federal Food, Drug, and Cosmetic Act	21 CFR 1-1702

TOXICS-RELATED ACTIVITIES*

Meat and Poultry Inspection Program

The basic purpose of the Meat and Poultry Inspection Program (MPI) is to assure safe meat and poultry products for consumers. Authority under the meat and poultry inspection acts to regulate and perform inspections begins when livestock or poultry arrive at slaughter plants. At this time, inspectors evaluate animals for exposure to drugs, pesticides, or other chemical adulterants. Should such adulteration be visibly detected, it is then retained by MPI and removed from consumer channels to prevent further marketing of the food. Immediately upon receipt of a violative result, the MPI region notifies FDA, State Department of Agriculture, EPA (for pesticides), MPI inspectors, and the producer, that a violation occurred and informs them of the followup actions that will be taken by MPI. Followup actions usually require that additional animals from the particular farm be retained at slaughter pending testing to confirm that adequate remedial action has been taken. Also, agencies regulating drug and pesticide usage have the opportunity to investigate why regulations were violated. The resulting investigation reports give FDA and EPA insight into where potential program changes may be beneficial.

Meat and Poultry Residue Program (MPR)

The Federal Meat Inspection Act and the Poultry Products Inspection Act authorize the United States Department of Agriculture (Meat and Poultry Inspection Program) to inspect meat and poultry prepared for transportation or sale in interstate commerce. Routine antemortem and postmortem inspection cannot usually detect the presence or absence of a chemical or drug residue unless clinical signs are present. This makes laboratory analysis of tissues vital in obtaining information for dissemination to the Federal and State Agencies in controlling potential adulterants of the meat and poultry supply.

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*Included here are those activities identified as toxics-related from the information provided by each agency or office at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions, as well as new additions, to the attention of the Office of Pesticides and Toxic Substances, Chemical Coordination Staff.

The Meat and Poultry Inspection (MPI) Program has developed a system to determine the existence of toxic residue problems and provide an active exchange with other government agencies and producers. There is a twofold effort on the part of MPI to control residues. In the first part, the monitoring phase is designed to randomly select and analyze edible tissues from animals and poultry for residues. This provides the needed information for incidences, trends, and compliance with tolerances. It has a 95 percent probability of detecting a residue when 1 percent or more of the animals or poultry going to slaughter contain detectable levels. It is not designed to detect and condemn violative products. However, the program identifies and reflects on production practices that utilize drugs and chemicals for the much-needed meat supply.

Marketing practices before and after slaughter emphasize why monitoring programs cannot do more. Marketing would be a catastrophe if all products were held until analyses were completed for all possible residues. Least of all, the need for holding facilities to prevent loss of a product in itself would eliminate a "fresh" product from the market.

The Residue Monitoring Program supports FSIS inspection programs to help assure a wholesome meat and poultry supply. The Monitoring Program can only help identify problems; it has no power to correct. Correction is obtained through surveillance, educational, and regulatory programs. These programs provide both short-term and more permanent solutions.

Surveillance programs are basically of two types. First, there is the Contamination Response System, triggered when there is a finding of a residue which has the potential for widespread problems with the meat and poultry supply. Under this system, the agency determines the extent of the contamination by working with other agencies and using sampling programs when indicated. In other cases, a routine agency followup program is required, involving pretesting before release of animals or poultry.

The second type, called the Exploratory Surveillance Program, is used to determine if a potential problem may exist. This is specially designed to obtain answers to specific questions, such as whether the analytical method used gives reliable results on samples from multiple sources, or whether a compound used under specific commercial conditions results in a residue problem.

Based on knowledge gained from tracking residue problems to their sources, FSIS believes that violative residues can be prevented. FSIS has joined with the Extension Service, producer groups, and regulatory agencies in a new cooperative education effort called the Residue Avoidance Program, which is designed to help farmers identify points in their production systems where chemical and drug contamination can occur and become a problem.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

200 Independence Ave SW.
Washington, D.C. 20201

Locator: 202-245-6296
Information: 202-245-6343

On Sunday, May 4, 1980, the Department of Health and Human Services (DHHS) came into being as a result of the separation of the Department of Education from the 27-year-old Department of Health, Education, and Welfare. The new department was created by the Department of Education Organization Act, signed by President Carter on October 17, 1979, which provided for establishment of a separate Department of Education.

DHHS has a proposed fiscal 1981 budget of some $226 billion and is responsible for almost 300 programs conducted by 140,000 full-time employees working throughout the United States and the world. DHHS is the Federal Government's principal agency for furthering the good health of Americans and providing them with essential human services.

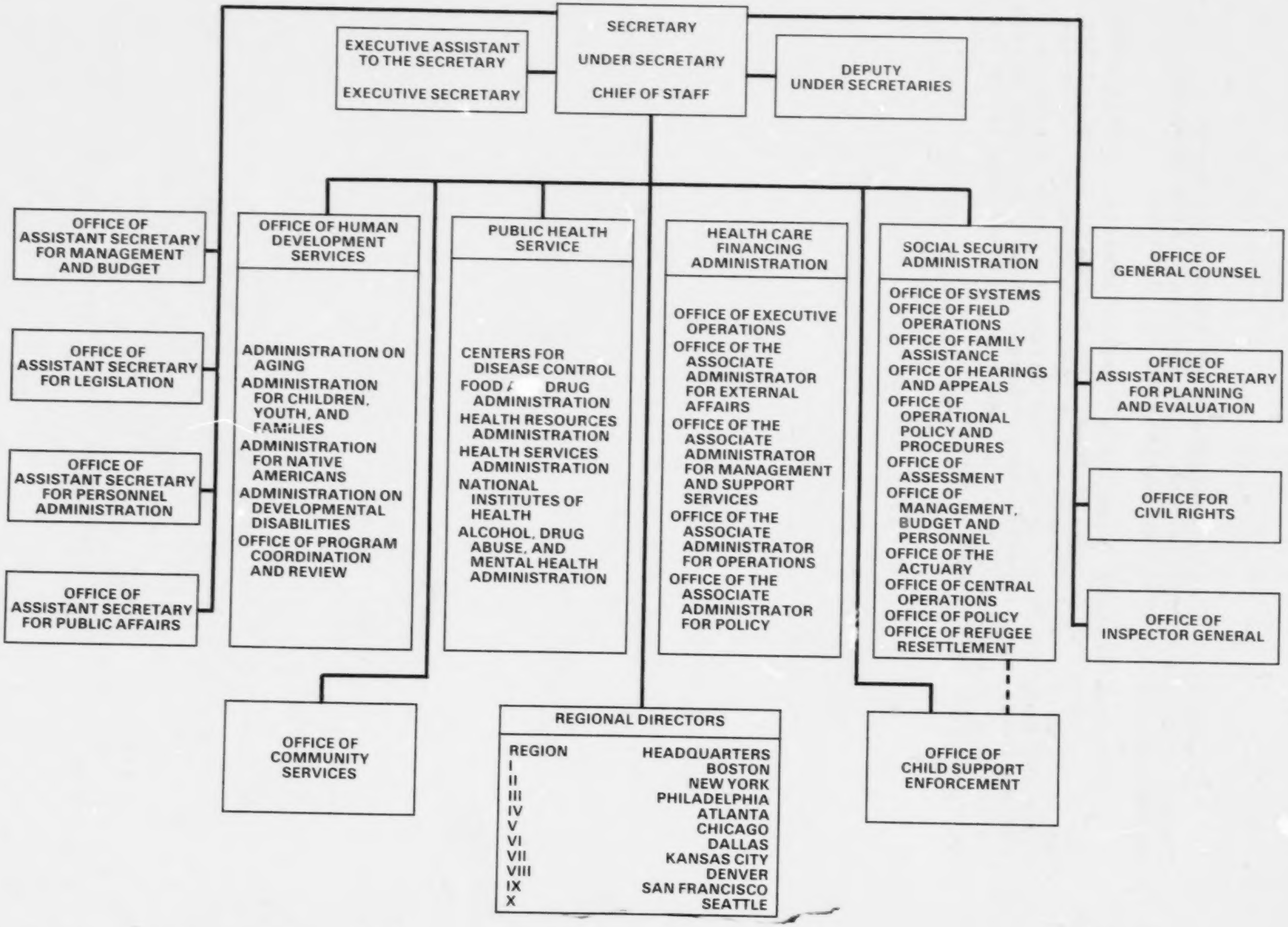
The new Department has four principle components:

- The Public Health Service conducts research, combats illness and disease, ensures safety of food and drugs, and supports and develops health care resources.
- The Health Care Financing Administration assists Americans in obtaining health care.
- The Office of Human Development Services provides social services to millions of needy Americans through Federal/State programs.
- The Social Security Administration administers the Social Security program, the Supplemental Security Income program, and the Aid to Families of Dependent Children program.

In addition to the activities of these four major components, DHHS administers a refugee assistance program authorized by the Refugee Assistance Act of 1980.

This publication highlights several agencies within DHHS. These include the Bureau of Food, the Bureau of Drugs and the National Center for Toxicological Research located within the Food and Drug Administration; the National Cancer Institute and the National Institute of Environmental Health Sciences of the National Institutes of Health; and the National Institute for Occupational Safety and Health.

DEPARTMENT OF HEALTH AND HUMAN SERVICES


SECRETARY
UNDER SECRETARY
CHIEF OF STAFF
EXECUTIVE ASSISTANT TO THE SECRETARY
EXECUTIVE SECRETARY
DEPUTY UNDER SECRETARIES
OFFICE OF ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
OFFICE OF ASSISTANT SECRETARY FOR LEGISLATION
OFFICE OF ASSISTANT SECRETARY FOR PERSONNEL ADMINISTRATION
OFFICE OF ASSISTANT SECRETARY FOR PUBLIC AFFAIRS
OFFICE OF HUMAN DEVELOPMENT SERVICES
ADMINISTRATION ON AGING
ADMINISTRATION FOR CHILDREN, YOUTH, AND FAMILIES
ADMINISTRATION FOR NATIVE AMERICANS
ADMINISTRATION ON DEVELOPMENTAL DISABILITIES
OFFICE OF PROGRAM COORDINATION AND REVIEW
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
FOOD AND DRUG ADMINISTRATION
HEALTH RESOURCES ADMINISTRATION
HEALTH SERVICES ADMINISTRATION
NATIONAL INSTITUTES OF HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
HEALTH CARE FINANCING ADMINISTRATION
OFFICE OF EXECUTIVE OPERATIONS
OFFICE OF THE ASSOCIATE ADMINISTRATOR FOR EXTERNAL AFFAIRS
OFFICE OF THE ASSOCIATE ADMINISTRATOR FOR MANAGEMENT AND SUPPORT SERVICES
OFFICE OF THE ASSOCIATE ADMINISTRATOR FOR OPERATIONS
OFFICE OF THE ASSOCIATE ADMINISTRATOR FOR POLICY
SOCIAL SECURITY ADMINISTRATION
OFFICE OF SYSTEMS
OFFICE OF FIELD OPERATIONS
OFFICE OF FAMILY ASSISTANCE
OFFICE OF HEARINGS AND APPEALS
OFFICE OF OPERATIONAL POLICY AND PROCEDURES
OFFICE OF ASSESSMENT
OFFICE OF MANAGEMENT, BUDGET AND PERSONNEL
OFFICE OF THE ACTUARY
OFFICE OF CENTRAL OPERATIONS
OFFICE OF POLICY
OFFICE OF REFUGEE RESETTLEMENT
OFFICE OF GENERAL COUNSEL
OFFICE OF ASSISTANT SECRETARY FOR PLANNING AND EVALUATION
OFFICE FOR CIVIL RIGHTS
OFFICE OF INSPECTOR GENERAL
OFFICE OF COMMUNITY SERVICES
REGIONAL DIRECTORS
OFFICE OF CHILD SUPPORT ENFORCEMENT

REGION	HEADQUARTERS
I	BOSTON
II	NEW YORK
III	PHILADELPHIA
IV	ATLANTA
V	CHICAGO
VI	DALLAS
VII	KANSAS CITY
VIII	DENVER
IX	SAN FRANCISCO
X	SEATTLE

FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Secretary's Office

Locator: 301-443-1544
Information: 301-443-1544

Organization....................page 62
Regulatory Authority............page 71

The Food and Drug Administration, part of the Public Health Services, is the Nation's oldest and principal consumer protection agency. FDA's mission is to ensure that food is safe, pure and wholesome; that human and animal drugs, biological products, and therapeutic devices are safe and effective; and that radiological products and use procedures do not result in unnecessary exposure to radiation. To carry out this mission, the FDA administers several laws, including the Federal Food, Drug and Cosmetic Act, and several specific provisions of the Public Health Service Act.

FDA employs over 7,000 people and is organized along product lines within seven primary organizational units: Office of the Commissioner, Bureau of Foods, Bureau of Veterinary Medicine, National Center for Drugs and Biologics, the National Center for Devices and Radiological Health, the National Center for Toxicological Research, and the field force which reports to the Associate Commissioner for Regulatory Affairs.

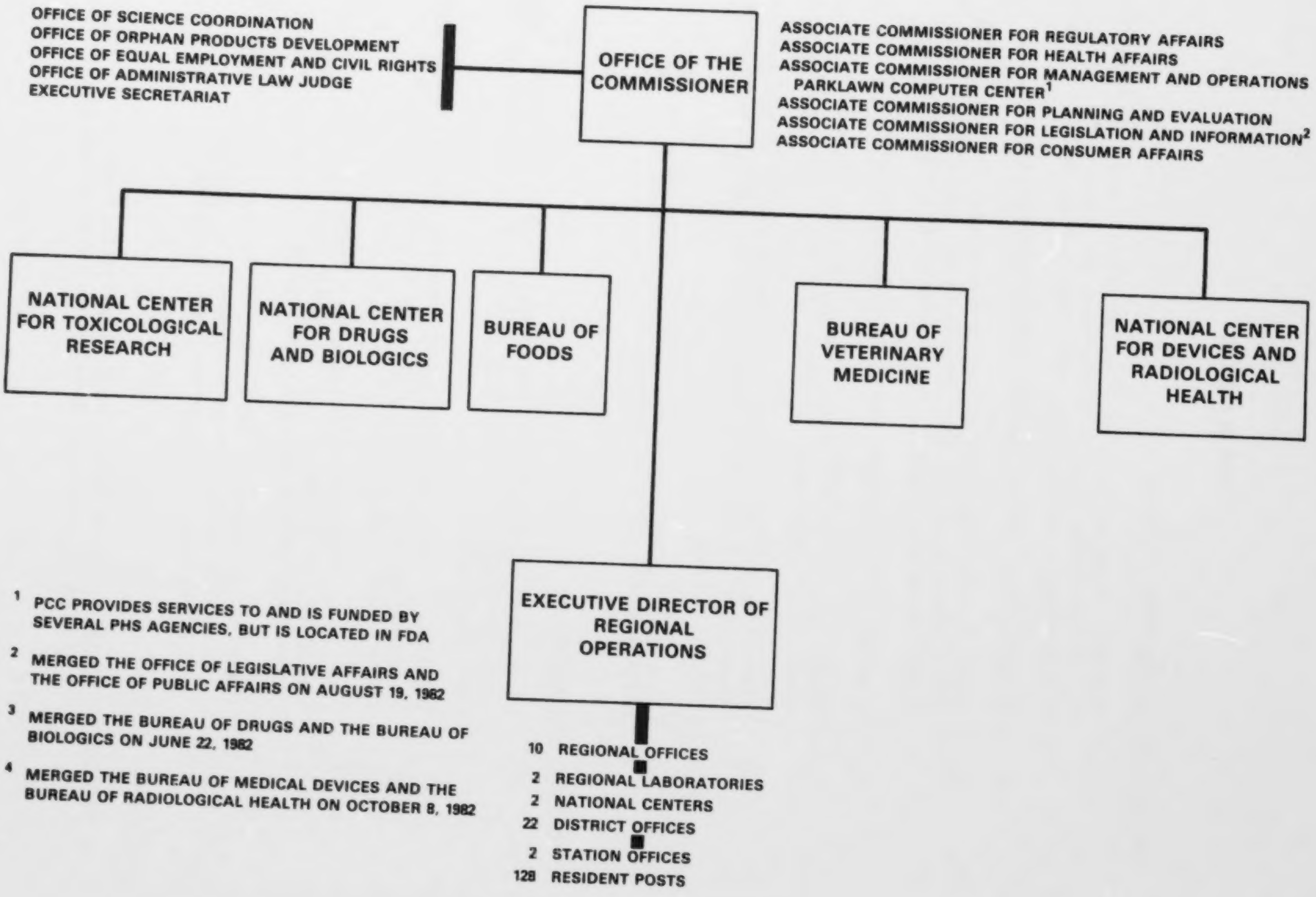
Approximately 60 percent of FDA's employees work at the FDA headquarters operations in the Washington, D.C., metropolitan area. Work at headquarters includes the approval of drugs (human and animal), medical devices, and food and color additives; research on analytical and regulatory science; and various compliance activities.

The remainder of FDA's workforce is located in ten regional offices, 21 district offices, and 124 resident stations. Most field employees inspect firms that produce regulated products and analyze product samples. They work out of district offices and resident posts, both of which feature field laboratories set up to perform a variety of analytical tests for measuring compliance with the law.

For fiscal year 1983, FDA's budget was 362 million dollars, and the Agency has proposed an FY 84 budget for 385.4 million dollars.

FOOD AND DRUG ADMINISTRATION

FY 83 $362 MILLION
7275 EMPLOYEES



OFFICE OF SCIENCE COORDINATION
OFFICE OF ORPHAN PRODUCTS DEVELOPMENT
OFFICE OF EQUAL EMPLOYMENT AND CIVIL RIGHTS
OFFICE OF ADMINISTRATIVE LAW JUDGE
EXECUTIVE SECRETARIAT

OFFICE OF THE COMMISSIONER

ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS
ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS
ASSOCIATE COMMISSIONER FOR MANAGEMENT AND OPERATIONS
  PARKLAWN COMPUTER CENTER[1]
ASSOCIATE COMMISSIONER FOR PLANNING AND EVALUATION
ASSOCIATE COMMISSIONER FOR LEGISLATION AND INFORMATION[2]
ASSOCIATE COMMISSIONER FOR CONSUMER AFFAIRS

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

NATIONAL CENTER FOR DRUGS AND BIOLOGICS

BUREAU OF FOODS

BUREAU OF VETERINARY MEDICINE

NATIONAL CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS

10	REGIONAL OFFICES
2	REGIONAL LABORATORIES
2	NATIONAL CENTERS
22	DISTRICT OFFICES
2	STATION OFFICES
128	RESIDENT POSTS

[1] PCC PROVIDES SERVICES TO AND IS FUNDED BY SEVERAL PHS AGENCIES, BUT IS LOCATED IN FDA

[2] MERGED THE OFFICE OF LEGISLATIVE AFFAIRS AND THE OFFICE OF PUBLIC AFFAIRS ON AUGUST 19, 1982

[3] MERGED THE BUREAU OF DRUGS AND THE BUREAU OF BIOLOGICS ON JUNE 22, 1982

[4] MERGED THE BUREAU OF MEDICAL DEVICES AND THE BUREAU OF RADIOLOGICAL HEALTH ON OCTOBER 8, 1982

ORGANIZATION[*]

OFFICE OF REGULATORY AFFAIRS

- Assists Commissioner and other officials on regulations and compliance issues that have an impact on policy development, execution, and long-range program goals.
- Establishes and enforces compliance policy.
- Acts as liaison with other Federal agencies on FDA compliance matters and coordinates Agencywide voluntary compliance and industry information activities.
- Directs and coordinates FDA regulatory process.
- Evaluates proposed legal actions to ascertain compliance with regulatory policy and enforcement objectives.
- Coordinates development of new or novel Agencywide compliance programs, such as bio-research monitoring activities.
- Monitors compliance activities to ensure uniform application of FDA policy.

OFFICE OF PLANNING AND EVALUATION

- Develops program and planning strategy through analysis and evaluation of issues affecting policies and program performance.
- Initiates and monitors the Agencywide planning system including the 5-year plan, strategic plan, and functional plans.
- Conducts operations research, economic and special studies as a basis for forecasting trends, needs, and problems requiring FDA solutions or involvement.
- Evaluates impacts of external factors on FDA programs, including industry and economics, consumer expectations, and protective legislation.

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*Note: Only those offices that deal with toxics or toxics-related issues are developed in this section.

- Recommends new programs, changes in existing programs, and program priorities.
- Develops systems to evaluate FDA program accomplishments.
- Evaluates impact of FDA programs on consumer protection.
- Manages the FDA Evaluation Review Board.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)

1. National Center for Toxicological Research - Overall Functions
2. Authority and Effective Date

1. NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH - OVERALL FUNCTIONS (HFT).

a. Conducts research programs to study the biological effects of potentially toxic chemical substances found in man's environment, emphasizing: the determination of the adverse health effects resulting from long-term, low-level exposure to chemical toxicants, determination of the basic biological processes for chemical toxicants in animal organisms, development of improved methodologies and test protocols for evaluating the safety of chemical toxicants, and development of data to facilitate the extrapolation of toxicological data from laboratory animals to man.

b. Conducts additional research programs which utilize facilities and expertise of the Center and contribute to its overall scientific capability.

c. Develops Center programs as a national resource in close cooperation with other agencies in the Public Health Service and the Environmental Protection Agency (EPA) and under the National Toxicology Program.

d. Operates with the advice of a Policy Board, consisting of members appointed by the Secretary of Health and Human Services and by the Administrator, EPA. The NCTR Policy Board recommends program priorities, reviews program and research results, reviews budget requirements and allotments, recommends management policies, reviews qualifications of applicants for key positions, and advises agency heads on matters concerning the Center.

2. AUTHORITY AND EFFECTIVE DATE. The functional statements for the Center were approved by the Secretary of Health and Human Services and published in the Federal Register (44 FR 11273) on February 28, 1979.

NATIONAL CENTER FOR DRUGS AND BIOLOGICS

1. National Center for Drugs and Biologics - Overall Functions
2. Authority and Effective Date

1. NATIONAL CENTER FOR DRUGS AND BIOLOGICS - OVERALL FUNCTIONS (HFN).

a. Develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs and biologicals for human use.

b. Plans and conducts research related to the development, manufacture, testing, and use of both new and old biological products to develop a scientific base for establishing standards designed to ensure the continued safety, purity, potency, and efficacy of biological products.

c. Inspects manufacturer's facilities for compliance with standards, tests products submitted for release, establishes written and physical standards, and approves licensing of manufacturers to produce biological products.

d. Reviews and evaluates new drug applications (NDA's) and notices of claimed investigational exemption for new drugs (IND's).

e. Develops and implements standards for the safety and effectiveness of all over-the-counter (OTC) drugs.

f. Monitors the quality of marketed drugs and biologicals through product testing, surveillance, and compliance programs.

g. Develops and promulgates guidelines on current Good Manufacturing Practices for use by the biological and drug industry.

h. Develops and disseminates information and educational material dealing with biologicals and drugs to the medical community and the public, in coordination with the Office of the Commissioner.

i. Conducts research and develops scientific standards on the composition, quality, safety, and efficacy of human drugs.

BUREAU OF VETERINARY MEDICINE

1. Bureau of Veterinary Medicine - Overall Functions
2. Authority and Effective Date

1. BUREAU OF VETERINARY MEDICINE - OVERALL FUNCTIONS (HFV).

   a. Develops and recommends the veterinary medical policy of the Food and Drug Administration with respect to the safety and efficacy of animal drugs, feed additives, and devices.

   b. Evaluates, for animal safety and efficacy, proposed and marketed animal drugs and feed additives and marketed devices for animal use.

   c. Coordinates the veterinary medical aspects of the FDA inspection and investigational programs and provides veterinary medical opinions in drug hearings and court cases.

   d. Plans, directs, and evaluates FDA's surveillance and compliance programs relating to animal drugs, animal feeds, and other veterinary medical matters.

   e. In cooperation with other Agency components, provides FDA policy development and direction on environmental impact matters.

2. AUTHORITY AND EFFECTIVE DATE. The functional statements for the Bureau were approved by the Secretary of Health and Human Services and published in the Federal Register (47 FR 3608) on January 26, 1982.

BUREAU OF FOODS

1. Bureau of Foods - Overall Functions
2. Authority and Effective Date

1. BUREAU OF FOODS - OVERALL FUNCTIONS (HFF).

a. Develops FDA policy with respect to the safety, composition, quality (including nutrition), and labeling of foods, food additives, colors, and cosmetics.

b. Conducts research and develops standards on the composition, quality, and safety of foods, food additives, colors, and cosmetics.

c. Conducts research designed to improve the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, food additives, colors, and cosmetics.

d. Develops and promulgates current good manufacturing practices for the food processing industry and model ordinances, codes, and model regulations for State and local government use in assuring food safety and quality.

e. Plans FDA surveillance and compliance programs and evaluates progress toward objectives of planned program and regulatory activities relating to foods, food additives, colors, and cosmetics.

f. Reviews industry petitions and recommends promulgation of regulations for food standards and for the safe use of color and food additives.

g. Collects and interprets data on nutrition, food additives, and environmental factors affecting the total chemical insult posed by direct and indirect food additives.

h. Analyzes regulatory samples as necessary to support Bureau compliance programs.

i. Participates in training of FDA field personnel and provides guidance to the regulated industries in the application of the most effective procedures to assure food safety and quality.

NATIONAL CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

1. National Center for Devices and Radiological Health - Overall Functions
2. Authority and Effective Date

1. NATIONAL CENTER FOR DEVICES AND RADIOLOGICAL HEALTH - OVERALL FUNCTIONS (HFW).

a. Develops and carries out a national program designed to control unnecessary exposures of humans to, and assure the safe and efficacious use of, potentially hazardous ionizing and nonionizing radiation.

b. Develops policy and priorities regarding FDA programs relating to the safety, effectiveness, and labeling of medical devices for human use.

c. Conducts an electronic product radiation control program including the development and administration of performance standards.

d. Develops, plans, and evaluates surveillance and compliance programs for medical devices and radiation exposure.

e. Plans, conducts, and supports research and testing relating to medical devices and to the health effects of radiation exposure.

f. Reviews and evaluates medical device premarket approval applications (PMAA's), product development protocols (PDP's), and exemption requests for investigational devices (IDE's).

g. Develops, promulgates, and enforces performance standards for appropriate categories of medical devices and Good Manufacturing Practice (GMP) regulations for manufacturers.

h. Provides technical and other nonfinancial assistance to small manufacturers of medical devices.

i. Develops regulations, standards, and criteria and recommends changes in FDA legislative authority necessary to protect the public health.

j. Provides scientific and technical support to other components within FDA and other agencies on matters relating to radiological health and medical devices.

k. Maintains appropriate liaison with other Federal, State, and international agencies, with industry, and with consumer and professional organizations.

2. AUTHORITY AND EFFECTIVE DATE. The functional statements for this Center were approved by the Secretary of Health and Human Services and published in the Federal Register (47 FR 44615) on October 8, 1982.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone*	Mail Stop
Office of Regulatory Affairs	301-443-1594	HFC-1
Bureau of Veterinary Medicine	301-443-3450	HFV-1
Bureau of Foods	202-245-1057	HFF-1
National Center for Drugs and Biologics	301-443-2894	HFN-1

Include All Bureaus and Centers (NCDRH, NCTR, etc.)

REGIONAL AND FIELD OFFICES

Division/Office	Phone	Mail Stops
Regional Food and Drug Director	617-223-1278 FTS: 8-223-1278	Region I HFR-11 585 Commercial Street Boston, MA 02109
Regional Food and Drug Director	212-965-5416 FTS: 8-663-5416	Region II HFR-21 830 3rd Avenue Brooklyn, NY 11232
Regional Food and Drug Director	215-597-4390 FTS: 8-597-4390	Region III HFR-31 2nd and Chestnut Street Room 900 Philadelphia, PA 19106

*FTS numbers are the same.

FDA'S REGULATORY AUTHORITY

The Food and Drug Adminstration's authority is derived from laws passed by Congress and assigned to the U.S. Department of Health and Human Services (HHS). As an agency of the Department, FDA has been delegated the responsibility to implement these laws. Federal laws define the requirements applicable to business and industry dealing in interstate commerce, as well as the authority of the agency that will administer and enforce each law. The implementing agency must make rules--regulations--telling the affected industry and the public specifically how the law is to be applied.

FDA is responsible for enforcing a number of statutes, but three are especially important: The Food, Drug, and Cosmetic Act; the Public Health Service Act; and the Fair Packaging and Labeling Act.

The Food, Drug and Cosmetic Act (21 U.S.C. 301-392)--often called the FD&C Act

Enforcing the FD&C Act accounts for about 90 percent of FDA's workload. This statute and its amendments provide for the regulation of foods (including food additives), color additives, human and animal drugs (including medicated animal feeds), medical devices, and cosmetics. Generally, the Act gives FDA authority to regulate only those products which are in interstate commerce. Meat and poultry, however, are principally controlled by a separate statute enforced by the U.S. Department of Agriculture.

Imported products are also subject to the provisions of the FD&C Act. FDA inspectors and investigators inspect imports while the goods are still in the custody of the U.S. Customs Service; violative products may be detained. Their entry into this country may be permitted if the violation can be corrected (by reprocessing a food product, for example).

A model for most State food and drug laws, and even for those of other countries, the Act provides a number of regulatory controls. These include preventive measures such as premarket approvals and establishment of quality standards for various products; authority to monitor the marketplace by means of factory inspections and other surveillance; and several mechanisms, administrative and judicial, to correct problems

Violative conditions explicitly prohibited by the Act generally fall into two categories: adulteration and misbranding. In addition, the Act forbids violations of the new drug provisions and of the emergency permit controls applicable to certain foods. The FD&C Act provides three major legal sanctions against violations.

- Seizure of offending products is one such control; whole lots of a product may be taken into the custody of the U.S. courts and thereby kept off the market.
- FDA may also recommend criminal prosecution for the person and/or firm responsible for product violations.
- The third major control provided by the Act is the injunctions authority, whereby a Federal district court enjoins, or forbids, shipment of an offending product through interstate commerce. (The order could apply to all products prepared in a factory shown to be unsanitary or otherwise not meeting quality requirements. Injunctions or restraining orders may be preliminary, temporary, or permanent.)

The Public Health Service Act (PHS Act - 1944)

Three sections of the Act are enforced by FDA:

- 42 U.S.C. 262-263--The interstate sale of biological products such as vaccines, serums, and blood is regulated under this law. The products must be safe, pure, and potent. Blood banks and manufacturers of vaccines, serums, and antitoxins must be licensed by FDA. Among other requirements for licensing, the products must meet the standards for production and product testing established by FDA. FDA also tests the products, usually on a lot-by-lot basis. Biological products may also be defined as drugs or medical devices under the FD&C Act, and its sanctions can be applied (e.g., seizure, criminal prosecution, or injunction).
- 42 U.S.C 264--Under this section of the PHS Act, FDA ensures the safety of pasteurized milk and shellfish; the sanitation of food service operations; and the sanitation of the food, water, and sanitary facilities for travelers on interstate vessels, trains, planes, and buses.

- 42 U.S.C. 263b - 263n--Radiation Control for Health and Safety Act (1968 Amendment to the Public Health Sercie Act)

  This section protects the public from unnecessary exposure to radiation from electronic products such as color television sets, microwave ovens, and x-ray machines. FDA sets performance standards for these and similar products.

  Products meeting FDA standards are certified. In the case of defective products, the law provides that the manufacturer will repair, replace, or refund the cost of the products.

  In certain circumstances, radiological products are also medical devices, subject to requirements of the FD&C Act as well as the Radiation Control Act.

The Fair Packaging and Labeling Act (1966)

The law requires that product labels be honest and informative so consumers will know what they are buying and how to use it properly. The label must also state the manufacturer's or distributor's name and address. The Federal Trade Commission enforces this act for all products other than foods, drugs, medical devices, and cosmetics. The labeling for prescription drugs is controlled by sections of the Food, Drug, and Cosmetic Act.

Other Laws

FDA enforces several other Federal laws, including the Tea Importation Act and the Federal Import Milk Act, and a few food standards that were established by direct act of Congress--e.g., standards for butter and for nonfat dry milk. FDA also helps enforce the Controlled Substances Act by making recommendations to the Drug Enforcement Agency on the "scheduling" of drugs with a potential for abuse, placing limits on access to them. The principal Acts enforced by FDA can be found in the booklet Food and Drug Administration Acts, available from the Office of Consumer Affairs, Consumer Communications Staff (HFE-88). It contains the Federal Food, Drug, and Cosmetic Act; the Public Health Service Act, Biological Products; the Radiation Control for Health and Safety Act; and the Fair Packaging and Labeling Act. For a complete description of the legal requirements of products under FDA jurisdiction--in layman's terms--see

Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administation, HEW Publication No. (FDA) 79-1042. This little blue book is affectionately known at FDA as "Pub 2." It is also available from the Consumer Communications Staff (HFE-88).

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

Jefferson, Arkansas 72079

Locator: 501-541-4611
FTS-542-4611

Information: 501-541-4503
FTS-542-4503

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NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)

On February 1, 1971, President Richard Nixon announced that a new, major project aimed at investigating the health effects of a variety of chemicals would be established in the biological facilities on the Pine Bluff Arsenal. The new activity was to be known as the National Center for Toxicological Research (NCTR).

The Center was developed as a result of the growing recognition of two kinds of needs: (1) better approaches to the understanding of what the data acquired from experimental animals means for man; and (2) more extensive facilities for the safety evaluation of the many chemicals in man's surroundings.

The President stated that the Center would initially be administered by the Food and Drug Administration, but should be considered as a national resource for all of government, industry, and the academic community.

Research activities are directed at four specific goals:

- Determination of adverse effects resulting from long-term, low-level exposure to various chemical substances;
- Development of experimental data to facilitate extrapolation of laboratory results to man;
- Determination of basic biological processes in animals to provide a more accurate extrapolation of laboratory results to humans; and
- Development of improved methods and testing protocols for evaluating the relative safety of chemical substances.

Regulatory agencies are currently faced with a dilemma of providing reasonable protection to the population with an inadequate knowledge base with respect to the actual harm caused by exposure to toxic and potentially toxic chemicals. The purpose of the NCTR has been and is to continue to expand that knowledge base so that rational decisions can be made with respect to limiting exposure to these chemicals.

There are many who believe that, as a society, the desire to protect our members has outstripped our knowledge of the actual harm caused by chemical exposures. Clearly, a balance must be established between protecting society from harm and improving the quality of life through product development (and, therefore, increased risk). If the balance is tipped in favor of assuring knowledge of human harm prior to restrictive action, one would have to await years and perhaps generations of human exposure and, therefore, potential damage to thousands, if not millions, of people before one could assess actual human health hazards. If the balance is tipped in the direction of over-protection, one would restrict the use of chemicals at the first indication of possible harm. That indication may come from knowledge of similar compounds or may be as a result of indication of harm to laboratory animals or microorganisms. Carrying this philosophy to its logical conclusion, one quickly deprives society of needed chemicals and restricts its ability to advance for the common good, compete in international markets, and utilize advancing technology to improve the quality of life.

The balancing of these two concerns is difficult because knowledge is limited at this time. Current technology simply does not allow for the conduct of laboratory experiments which result in definitive knowledge about what effects exposure will have on a human's health.

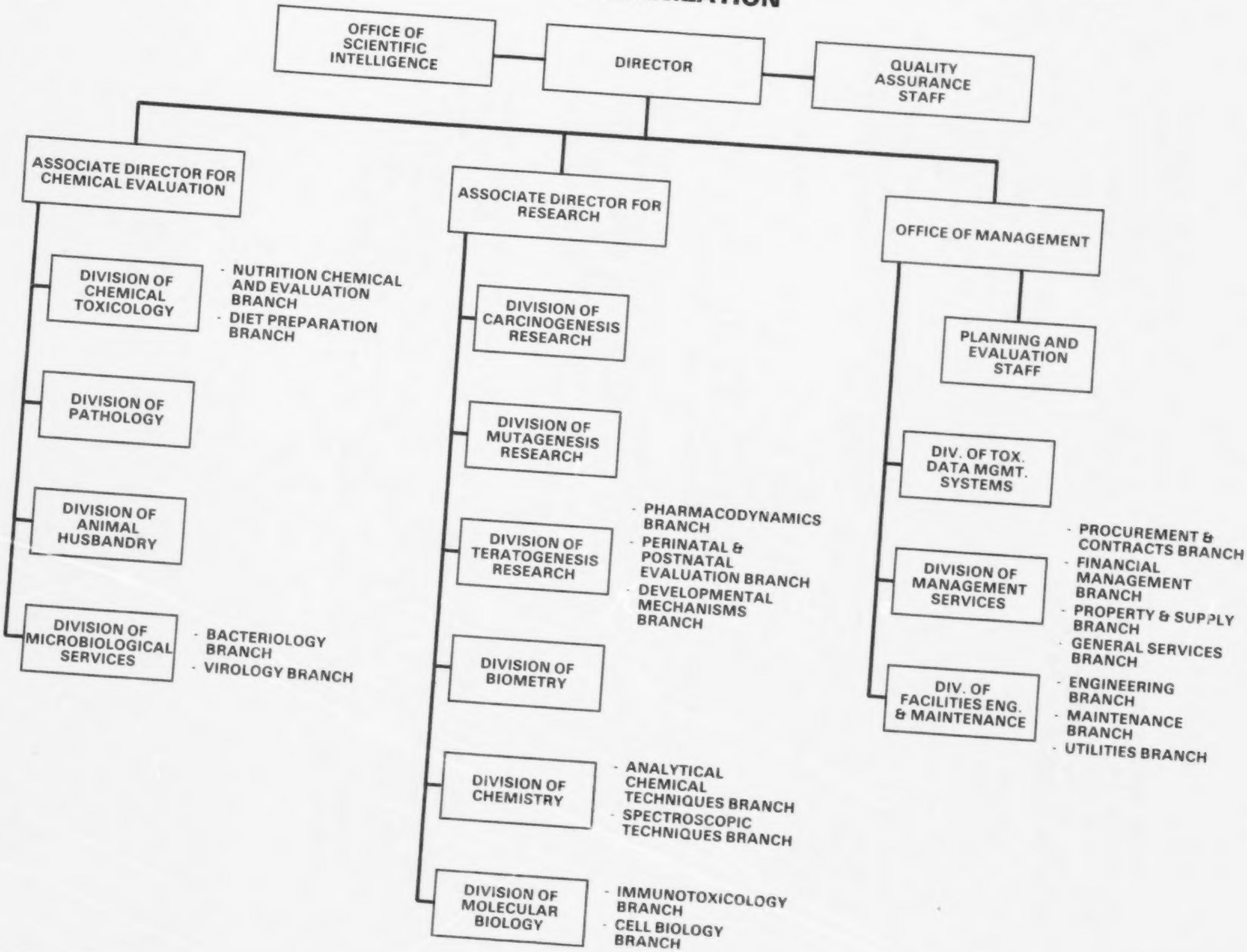
NCTR's purpose is to expand the knowledge base that can be of practical benefit to the regulatory agencies such that the necessary balancing can be accomplished with fewer unknowns. If we can extend knowledge to the point where we can clearly and accurately describe the harmful effects that will most likely occur upon exposure to chemicals, society will be in a much better position to decide if the benefits are more desirable than the harm caused by exposure. Without an improved knowledge base,society is simply unable to make rational determinations in these matters.

NCTR's approach to research is one of problem solving, not just problem finding. This approach can be categorized as follows: (1) leadership among the scientific community; (2) new programs of cooperation and consensus building among all sectors; and (3) close attention to maximizing its own productivity.

In the area of leadership among the scientific community, NCTR operates under the principle that in order for government science to be capable of solving difficult regulatory problems, it must do a better job of staying current with the rapid advancements emerging from academia and apply those advances to the currently existing regulatory problems.

With respect to developing new programs of cooperation, it is clear that the most significant advances will be accomplished by recognition of the best and most current scientific knowledge available. NCTR's approach to this problem is to identify purely scientific (as opposed to sociologic, economic, or political) aspects of the problem and identify those areas in which consensus can be attained across all relevant sectors.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)
ORGANIZATION


OFFICE OF SCIENTIFIC INTELLIGENCE
DIRECTOR
QUALITY ASSURANCE STAFF
ASSOCIATE DIRECTOR FOR CHEMICAL EVALUATION
DIVISION OF CHEMICAL TOXICOLOGY
- NUTRITION CHEMICAL AND EVALUATION BRANCH
- DIET PREPARATION BRANCH
DIVISION OF PATHOLOGY
DIVISION OF ANIMAL HUSBANDRY
DIVISION OF MICROBIOLOGICAL SERVICES
- BACTERIOLOGY BRANCH
- VIROLOGY BRANCH
ASSOCIATE DIRECTOR FOR RESEARCH
DIVISION OF CARCINOGENESIS RESEARCH
DIVISION OF MUTAGENESIS RESEARCH
DIVISION OF TERATOGENESIS RESEARCH
- PHARMACODYNAMICS BRANCH
- PERINATAL & POSTNATAL EVALUATION BRANCH
- DEVELOPMENTAL MECHANISMS BRANCH
DIVISION OF BIOMETRY
DIVISION OF CHEMISTRY
- ANALYTICAL CHEMICAL TECHNIQUES BRANCH
- SPECTROSCOPIC TECHNIQUES BRANCH
DIVISION OF MOLECULAR BIOLOGY
- IMMUNOTOXICOLOGY BRANCH
- CELL BIOLOGY BRANCH
OFFICE OF MANAGEMENT
PLANNING AND EVALUATION STAFF
DIV. OF TOX. DATA MGMT. SYSTEMS
DIVISION OF MANAGEMENT SERVICES
- PROCUREMENT & CONTRACTS BRANCH
- FINANCIAL MANAGEMENT BRANCH
- PROPERTY & SUPPLY BRANCH
- GENERAL SERVICES BRANCH
DIV. OF FACILITIES ENG. & MAINTENANCE
- ENGINEERING BRANCH
- MAINTENANCE BRANCH
- UTILITIES BRANCH

APPROVED SEPTEMBER 21, 1982

ORGANIZATION*

DIRECTOR FOR NCTR

- Oversees Center activities and research efforts.
- Maintains liaison with representatives from the scientific and research communities.
- Coordinates NCTR programs with the activities of the Environmental Protection Agency, Food and Drug Administration, National Institutes of Health, National Toxicology Program, Department of Defense Agencies, Consumer Product Safety Commission, and Department of Agriculture.
- Monitors performance of the Center's supporting contractors.
- Implements Departmental research policies.
- Directs research programs in developing biomarkers at the molecular level, permitting more rational bases for extrapolating animal data to human health effects.

Office of Scientific Intelligence

- Provides services to NCTR as a liaison and focal point on matters pertaining to the National Toxicology Program (NTP) and the World Health Organization (WHO).
- Participates in compound nominations and selections for chemical evaluations for the NTP and prepares Executive Summaries on compound use, population exposure, and safety evaluations or research performed on selected compounds.
- Conducts chemical evaluations on selected NTP compounds.

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*NOTE: Only those offices which deal with toxics or toxic-related issues are developed in this section.

ASSOCIATE DIRECTOR FOR RESEARCH

Division of Carcinogenesis Research

- Conducts research to utilize gene patterns and specific mutations in developing *in vivo* toxicological assay systems.
- Engages in research to determine the metabolic activation of chemical toxicants.
- Identifies the nature of damage to cellular constituents by activated chemical toxicants.
- Investigates the effects of cellular repair mechanisms of the toxic response.
- Determines critical detoxification pathways.
- Elucidates biochemical mechanisms by which chemical carcinogenesis is initiated and expressed.
- Evaluates compounds of regulatory interest with regard to mechanisms of action.

Division of Mutagenesis Research

- Estimates the risk to humans from exposure to chemicals in the environment.
- Develops methods to measure both microlesions (single gene mutations or small deletions) and macrolesions (serious chromosomal aberrations) for use in toxicology and safety evaluations.
- Works to improve short-term, *in vivo* bioassays for identifying the effects of toxic substances on genes.
- Focuses research on developing reliable and economical methods for evaluating the genotoxic potential of chemicals. Results are then used to identify the chemical risk to humans.

Division of Teratogenesis Research

- Develops sound information bases of comparative pharmacokinetics and metabolism to define valid mathematical models for extrapolation of animal data to man.
- Expands knowledge of basic developmental processes which can be affected by toxicants and defines mechanisms of teratogenicity.
- Develops and validates improved procedures for detecting the full range of possible toxic manifestations throughout the lifespan of the organism.
- Manages the teratology portion of the National Toxicology Program.
- Currently conducts four major projects: the Behavioral Teratology Collaborative Study; Reliability of Animal Models in Teratology; Development and Use of Mathematical Extrapolation Models in Teratogenesis; and Utility of Fetal Histopathology in Teratology Testing.

Division of Biometry

- Performs statistical analyses to support NCTR experimental programs.
- Develops statistical hypotheses for researchers and provides criteria for establishing the validity of statistical analyses performed at the Center.
- Maintains liaison with Environmental Protection Agency, Food and Drug Administration, National Institutes of Health, and other organizations concerned with biometric applications to toxicology.

Division of Chemistry

- Develops chemical procedures for performing trace analysis of carcinogens, teratogens, mutagens, toxicants, and other substances, or their analogs and metabolites.
- Studies chemical behavior, dosage forms, safe use and disposal of chemicals.

- Develops data bases to assist in the compliance with Good Laboratory Practice (GLP) requirements.
- Develops analytical methods to ensure nutritional integrity and absence of harmful substances in animal diets.
- Determines concentrations of chemically dosed products.

Analytical Chemical Techniques Branch

- Develops techniques for improving the accuracy of trace-level chemical analyses.

Spectroscopic Techniques Branch

- Advances state-of-the-art technology and methodologies for trace-level analysis and detection of compounds at parts per billion levels employing mass and nuclear magnetic resonance (NMR) spectroscopy.
- Provides analytical services to Federal, state, and local government agencies in detection of trace levels of deleterious compounds (i.e., Dioxin).

Division of Molecular Biology

Immunotoxicology Branch

- Conducts research on immunotoxicants that suppress reactions to harmful organisms.
- Assesses the impact of chemical agents on natural defense and repair mechanisms.

Cell Biology Branch

- Analyzes cells from toxicologically damaged tissues.
- Develops techniques for early diagnosis of carcinogenic growths.
- Examines biological changes resulting from exposure to toxic chemical compounds.

ASSOCIATE DIRECTOR FOR CHEMICAL EVALUATION

Division of Chemical Toxicology

- Conducts research and evaluation efforts under the guidance of the National Chemical Toxicological Testing Program.
- Develops improved methods for toxicological evaluations.
- Performs research on chronic and subchronic toxicological effects with particular emphasis on dose-response relationships.
- Studies the correlations between nutrition and toxicity, and advises other NCTR offices on nutritional matters.

Nutrition Chemical and Evaluation Branch

- Conducts chronic and subchronic laboratory studies to determine carcinogenic and other harmful effects toxic chemicals.
- Performs research on how diet affects biological and biochemical processes that may alter carcinogenic and toxicological responses.

Diet Preparation Branch

- Mixes chemical compounds into animal feed for use in experimental diet studies.

Division of Pathology

- Studies laboratory animal responses to toxic and carcinogenic agents.
- Develops improved pathology techniques, methodologies, and morphologic classification.
- Provides scientific guidance to other NCTR programs concerning pathological evaluation of laboratory animal tissues/sera.

Division of Microbiological Services

- Develops improved procedures for using microorganisms to enhance chemical biodegradation.

- Provides microbiological services to support NCTR's toxicological operations.

ASSOCIATE DIRECTOR FOR MANAGEMENT

Division of Toxicology Data Management Systems

- Conceptualizes, develops, implements, and operates the Toxicology Data Management System (TDMS) for the National Toxicology Program (NTP) and at NCTR.
- Assists EPA Office of Testing and Evaluation in developing an automated data system, in accordance with TSCA guidelines.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone	Mail Stop
Division of Carcinogenesis Research	501-541-4204 FTS: 8-542-4204	HFT-110
Division of Mutagenesis Research	501-541-4496 FTS: 8-542-4496	HFT-120
Division of Teratogenesis Research	501-541-4304 FTS: 8-542-4304	HFT-130
Division of Biometry	501-541-4519 FTS: 8-542-4519	HFT-140
Division of Chemistry	501-541-4556 FTS: 8-542-4556	HFT-150
Spectroscopic Techniques Branch	501-541-4368 FTS: 8-542-4368	HFT-154
Division of Molecular Biology	501-541-4449 FTS: 8-542-4449	HFT-160
Immunotoxicology Branch	501-541-4491 FTS: 8-542-4491	HFT-163
Cell Biology Branch	501-541-4574 FTS: 8-542-4574	HFT-164
Division of Chemical Toxicology; Nutrition Chemical and Evaluation Branch	501-541-4551 FTS: 8-542-4551	HFT-210
Diet Preparation Branch	501-541-4385 FTS: 8-542-4185	HFT-213
Division of Pathology	501-541-4185 FTS: 8-542-4185	HFT-230
Division of Microbiological Services	501-541-4449 FTS: 8-542-4449	HFT-250

STATUTORY AUTHORITIES

NCTR received its authority through President Nixon's announcement on January 27, 1971, establishing the research center at Pine Bluff, Arkansas. Its implementing authority originates in an Interagency Agreement between the Department of Health, Education, and Welfare (now The Department of Health and Human Services, DHHS) and the Environmental Protection Agency (EPA) signed on April 1, 1971. The Interagency Agreement establishes the Center's mission, functions, structure, and research responsibilities. Statutory authority enabling the DHHS and the EPA to direct the Center's activities resides in the Presidential letter and in the general legislative requirements assigning to the Agencies toxics-related research responsibilities. These Acts include the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§348, 355; the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §135; the Clean Air Act, 42 U.S.C. §1857; the Solid Waste Disposal Act, 42 U.S.C. §3251; and the Federal Water Pollution Control Act, 33 U.S.C. §1151.

NATIONAL INSTITUTES OF HEALTH

Public Health Service
Department of Health and Human Services
Bethesda, MD 20205

Locator: 301-496-2351
Information: 301-496-2535

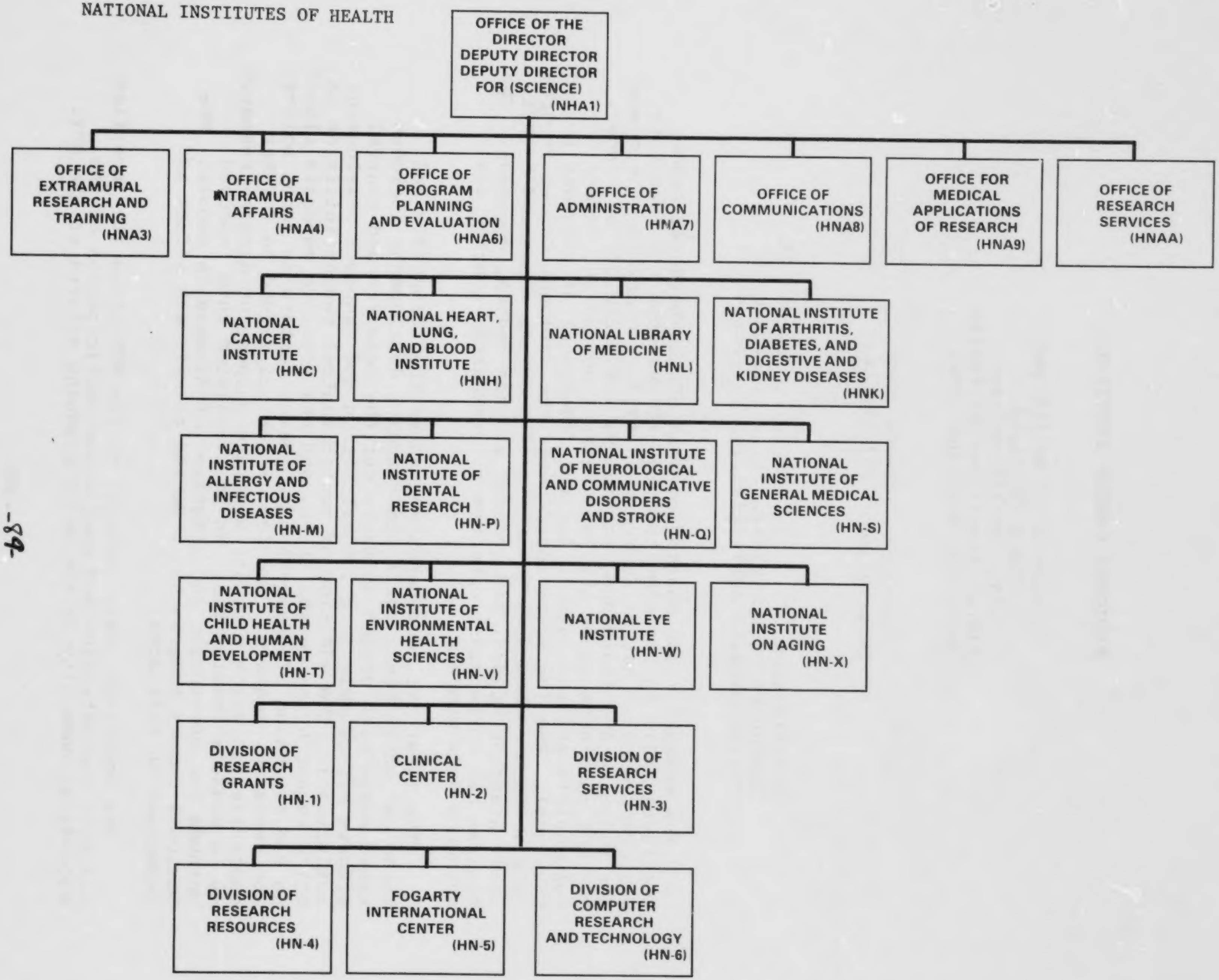
The National Institutes of Health (NIH), an agency of the Department of Health and Human Services (formerly the Department of Health, Education, and Welfare), provides leadership and direction to programs designed to improve human health through the following activities:

- o Conducts and supports research in the causes, diagnosis, prevention, and cure of diseases of man, in the processes of human growth and development, in the biological effects of environmental contaminants, and in related sciences.
- o Supports the training of research personnel, the construction of research facilities, and the development of other research resources.
- o Directs programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health specialists.

To carry out these functions, NIH is organized into 11 research Institutes, 4 Divisions, and the National Library of Medicine. The organization also includes a research hospital called the Clinical Center, and the Fogarty International Center, which fosters international biomedical exchange and provides facilities for foreign scholars in residence. NIH is headquartered in Bethesda, Maryland. However, one of its Institutes--the National Institute of Environmental Health Sciences--is at Research Triangle Park, North Carolina.

This publication will focus on the responsibilities and activities of two of the NIH Institutes--the National Cancer Institute and the National Institute of Environmental Health Sciences.

NATIONAL INSTITUTES OF HEALTH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OFFICE OF EXTRAMURAL RESEARCH AND TRAINING (HNA3)
OFFICE OF INTRAMURAL AFFAIRS (HNA4)
OFFICE OF PROGRAM PLANNING AND EVALUATION (HNA6)
OFFICE OF ADMINISTRATION (HNA7)
OFFICE OF COMMUNICATIONS (HNA8)
OFFICE FOR MEDICAL APPLICATIONS OF RESEARCH (HNA9)
OFFICE OF RESEARCH SERVICES (HNAA)
NATIONAL CANCER INSTITUTE (HNC)
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (HNH)
NATIONAL LIBRARY OF MEDICINE (HNL)
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES (HNK)
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (HN-M)
NATIONAL INSTITUTE OF DENTAL RESEARCH (HN-P)
NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE (HN-Q)
NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (HN-S)
NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (HN-T)
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (HN-V)
NATIONAL EYE INSTITUTE (HN-W)
NATIONAL INSTITUTE ON AGING (HN-X)
DIVISION OF RESEARCH GRANTS (HN-1)
CLINICAL CENTER (HN-2)
DIVISION OF RESEARCH SERVICES (HN-3)
DIVISION OF RESEARCH RESOURCES (HN-4)
FOGARTY INTERNATIONAL CENTER (HN-5)
DIVISION OF COMPUTER RESEARCH AND TECHNOLOGY (HN-6)

NATIONAL CANCER INSTITUTE

Department of Health and
Human Services
Public Health Service
National Institutes of Health
Bethesda, Maryland 20205

Locator: 301-496-4000
Information: 301-496-6641

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The essential and continuing goal of the National Cancer Institute (NCI) is the same today as it was when the Institute was created by an Act of Congress in 1937: To develop the means for reducing the incidence, morbidity, and mortality of cancer. The NCI continues to be the lead Federal agency in cancer, responsible and accountable for the investment of progress toward that goal. The Institute coordinates the National Cancer Program (NCP), which encompasses a variety of programs sponsored by NCI, other branches of NIH, and Federal and non-Federal agencies. The Program has three major components: research, control and resource development.

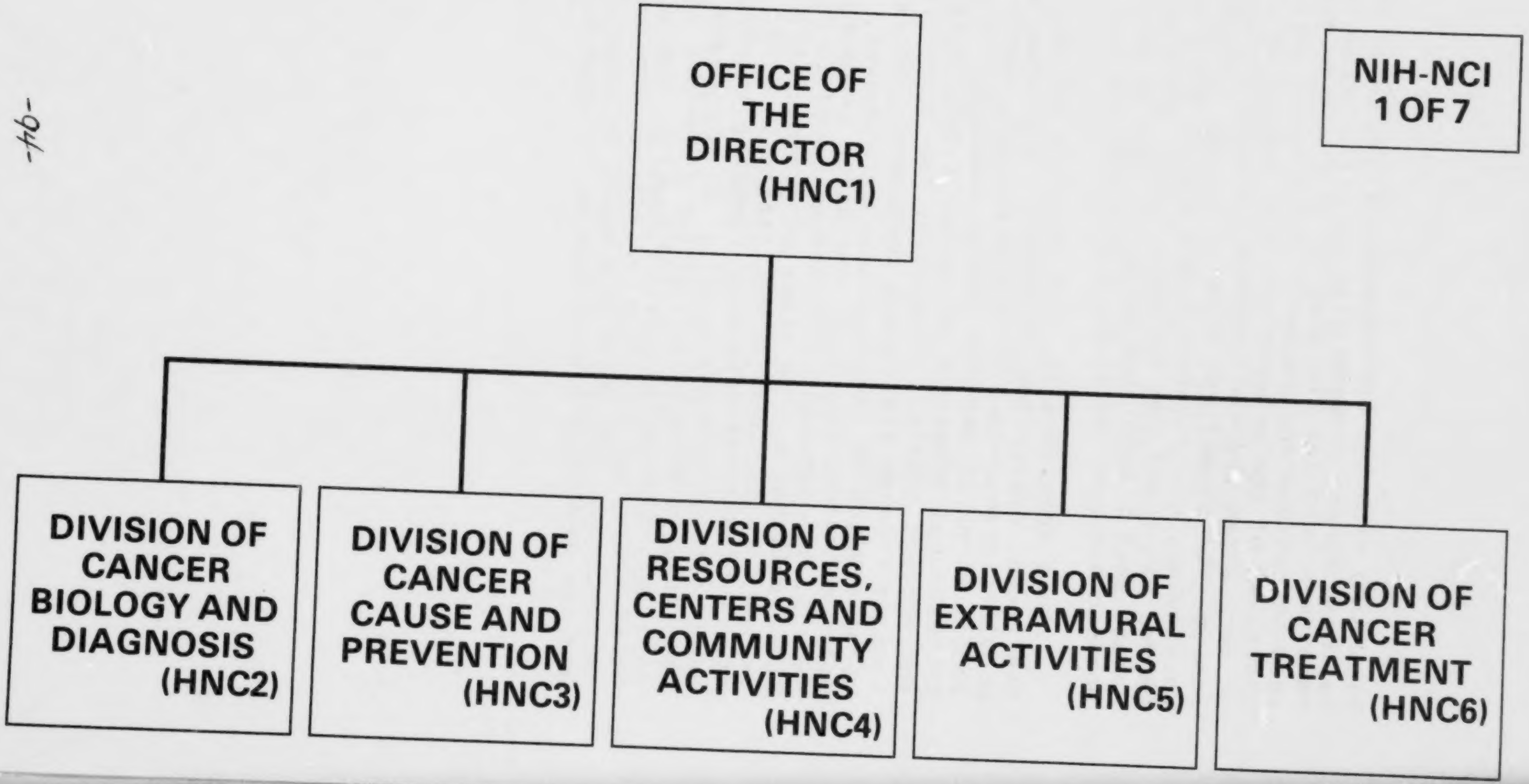
The first two components encompass the scientific and technical activities, while the resource development includes those activities needed to carry out the research and control efforts effectively (e.g., construction and manpower development activities). The addition of cancer control responsibilities to NCI's research responsibilities, and the specific emphasis placed on the expansion of comprehensive cancer centers as focal points for research, teaching, and demonstration, served to further emphasize the axiom that the ultimate purpose of disease research is to produce results that can be translated into improved methods for prevention and treatment of disease in people. The National Cancer Program has invested significant effort and resources in this area.

One important characteristic of the NCP since its inception has been the extensive and continuous participation of the biomedical community in the major planning efforts of the NCI.

Beginning with the development of the first edition of the National Cancer Program Plan in 1972, periodic planning sessions have been held for the purpose of revising and updating the major recommendations for research and control activities. The general character of the Program has also become increasingly a product of more extensive and frequent interaction among Congress, the public, the biomedical community, and Federal agencies. In particular, the consistent and active roles of the President's Cancer Panel and the National Cancer Advisory Board have established a model for effective and productive relationships between national advisory committees and the Federal agencies.

More specifically, NCI conducts and monitors research into the cause, prevention, diagnosis, and treatment of cancer and provides grants-in-aid to educational, public, or nonprofit institutions to perform cancer research. NCI also supports the professional education of cancer researchers through fellowships and project grants. Currently, the Institute is conducting, or funding through grants and contracts, laboratory and epidemiological studies on environmental carcinogens, including pesticides, motor exhausts, low-level radiation exposures, asbestos and other fibers, halogenated hydrocarbons found in drinking water, and other pollutants. In other programs, intra- and inter-species variability is under investigation in order to elucidate the causes of species-dependent response to carcinogen exposure; these efforts involve studies on carcinogen metabolism, pharmacokinetics, carcinogen-DNA adduct formation and DNA repair. In addition, food additives and natural components of foods are being evaluated for their ability to inhibit environmental carcinogens. NCI also acts as an information center on cancer and has developed a data bank on international cancer research.

NATIONAL CANCER INSTITUTE



NIH-NCI
1 OF 7

OFFICE OF
THE
DIRECTOR
(HNC1)

DIVISION OF
CANCER
BIOLOGY AND
DIAGNOSIS
(HNC2)

DIVISION OF
CANCER
CAUSE AND
PREVENTION
(HNC3)

DIVISION OF
RESOURCES,
CENTERS AND
COMMUNITY
ACTIVITIES
(HNC4)

DIVISION OF
EXTRAMURAL
ACTIVITIES
(HNC5)

DIVISION OF
CANCER
TREATMENT
(HNC6)

ORGANIZATION*

Note: NCI is currently undergoing reorganization. The materials presented here may be subject to change.

DIVISION OF CANCER AND PREVENTION (DCCP)

- Plans and directs a national program of basic research including laboratory, epidemiologic and biometric research on the cause and natural history of cancer and the means for preventing cancer through intramural research grants, cooperative agreements, and contracts.
- Evaluates the potential relationship between oncogenes and environmental carcinogenic agents in relation to the risk of cancer in humans.
- Serves as the focal point for the Federal Government on the synthesis of clinical, epidemiological, and experimental data relating to cancer causation.
- Advises the Director of NCI in evaluation of program activities relating to cancer causation and on grants and grant applications as they relate to cancer causes and prevention.

Carcinogenesis Intramural Program

- Plans, directs, and conducts a basic and applied research program on the occurrance and inhibition of cancer caused or promoted by chemical or physical agents separately or together, or in combination with biological agents.
- Develops and conducts programs in the areas of carcinogenesis and related toxicology, metabolism, chemistry, cell biology, and experimental tumor pathology.

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*Note: Only those offices which deal with toxics or toxics-related issues are developed in this section.

Field Studies and Statistics Program

- Plans, directs, and manages a program of epidemiologic, demographic, statistical and mathematical research on the distribution and occurrence of human cancer, and the identification of its characteristics and causes.
- Studies mortality and morbidity statistics, and makes correlations with demographic and environmental variables to formulate clues to cancer etiology.
- Performs field studies in an effort to detect the specific environmental and host determinants of cancer.

Office of the Director, DCCP

- Serves as a focal point for environmental/occupational cancer information and data through cooperative agreements and contracts.
- Maintains the primary monitoring and collaborative function for coordinating the NCI/EPA Collaborative Program on Environmental Cancer and the NCI/NIOSH Collaborative Program on Occupational Carcinogenesis.
- Compiles and distributes publications on carcinogens in drinking water, carcinogens in air pollutants, carcinogens in food, diet, drugs, and cosmetics.
- Conducts liaison activities for the National Cancer Program as it relates to the national effort on environmental and occupational cancer.

DIVISION OF RESOURCES, CENTERS AND COMMUNITY ACTIVITIES (DRCCA)

- Plans and conducts research, evaluation, demonstration, technology transfer, education and information dissemination programs to expedite the use of new information relevant to the prevention, detection, and diagnosis of cancer, and the pretreatment evaluation, treatment, rehabilitation, and the continuing care of cancer patients in the community and in cancer centers.
- Plans, directs, and coordinates the support of cancer research at cancer centers and through organ site programs.
- Supports professional and paraprofessional clinical education, research training, and continuing education.

- Administers project grant programs for the construction, alteration, renovation, and equipping of basic and clinical research facilities.
- Coordinates program activities with related activities in the other Divisions of NCI, the National Toxicology Program, other NIH Institutes, and other Federal and State agencies, and establishes liaison with professional and voluntary health agencies, labor organizations, and trade associations.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone*	Mail Stop
Director, NCI	301-496-5615	Building 31 Room 11A-52 Bethesda, MD 20205
Division of Cancer Cause and Prevention, NCI	301-496-6618	Building 31 Room 11A-03 Bethesda, MD 20205
Division of Resources, Centers and Community Activities, NCI	301-496-6616	Building 31 Room 4A-32 Bethesda, MD 20205
Division of Cancer Treatment, NCI	301-496-4291	Building 31 Room 3A-52 Bethesda, MD 20205
Division of Cancer Biology and Diagnosis, NCI	301-496-4345	Building 31 Room 3A-03 Bethesda, MD 20205
Division of Extramural Activities, NCI	301-496-5147	Building 31 Room 10A-03 Bethesda, MD 20205

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*FTS numbers are the same

STATUTORY AUTHORITIES

The National Cancer Institute Act

Public Law 75-244

This Act, passed by Congress and signed by President Roosevelt in 1937, established the National Cancer Institute. The purpose of the Act was "to provide for, foster, and aid in coordinating research relating to cancer." The Act also established the precedent for providing grants-in-aid to non-Federal scientists engaged in cancer research and created the National Cancer Advisory Council. This Act has been superseded by the National Cancer Act of 1971, which is dealt with below.

Key Sections of Act--Toxics Focus

sec. 1	Established NCI as a part of the Public Health Service.
sec. 2 (a,b)	Authorizes the Surgeon General to conduct and coordinate cancer research with other agencies, organizations, and individuals.
sec. 3	Created the National Cancer Advisory Council, a six-member council composed of "leading medical or scientific authorities."
sec. 4 (a,b,c)	Authorizes the Council to evaluate cancer-related research projects, to make information regarding these projects available to the public, and to review all applications for grants-in-aid.

The Public Health Services Act of 1944

Public Law 78-410 42 U.S.C. § 281

Enacted on July 1, 1944, the Public Health Services Act established the National Cancer Institute as a division of the National Institutes of Health and gave the Surgeon General broad powers to foster research relating to health and disease. The act also consolidated many NCI revisions into this single law.

Key Sections of Act--Toxics Focus

sec. 401	"The NCI shall be a division of the National Institutes of Health."
sec. 402	Foster and coordinate cancer research.
sec. 403	Transfers statutory authority for the administration of NCI from the National Cancer Institute Act of 1937 to the Public Health Services Act of 1944.
sec. 404	Transfers statutory authority for the National Cancer Advisory Council from the National Cancer Institute Act of 1937 to the Public Health Services Act of 1944.

The National Cancer Act of 1971

Public Law 92-218 42 U.S.C. §§ 281-286

This Act broadened the responsibilities and authorities of the NCI Director and initiated the National Cancer Program. The Act also created the international cancer research data bank and established a three-member President's Cancer Panel and the National Cancer Advisory Board.

Key Sections of Act--Toxics Focus

sec. 3(a)	Amends Part A of Title IV of the Public Health Services Act by adding after section 406 the following section regarding the "National Cancer Program."
sec. 407(a)	Authorizes the Director of NCI to coordinate all NIH activities related to cancer.
sec. 407(b)(1)	Initiates an expanded, intensified, and coordinated cancer research program.
sec. 407(b)(4)	Establishes "an international cancer research data bank to collect, catalog, store, and disseminate information regarding the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country."

sec. 407(c)(1)	Establishes the President's Cancer Panel, a three-member panel appointed by the president to appraise the National Cancer Program.
sec. 408	Provides the establishment of new cancer research and demonstration centers.

The National Cancer Act Amendments of 1974

Public Law 93-352 42 U.S.C. §§ 281-286

In addition to authorizing appropriations for Fiscal Years 1975-77, these amendments brought about improvements and changes in the National Cancer Program. Also, they established guidelines for the dissemination and interpretation of information on cancer research, directed the NCP to explore the role of nutrition in the treatment, rehabilitation, and causation of cancer, and removed the limits on the number of comprehensive cancer centers that could be initiated by the NCI.

Key Sections of Act--Toxics Focus

sec. 103	Directs NCI to include in the data bank information regarding "nutrition programs for cancer patients and the relationship between nutrition and cancer."
sec. 108	Authorizes NCI to contract for a specific program "to disseminate and interpret, on a current basis, for professionals and other health officials, scientists, and the general public," information on the cause, prevention, diagnosis, and treatment of cancer.

The National Cancer Act Amendments of 1977

Public Law 95-622 42 U.S.C. §§ 281-286

The National Cancer Institute mandate was extended for one year when the President signed the Health Planning and Health Services Research and Statistics Extension Act. The number of expert appointments was increased from 100 to 151 through this legislation.

The National Cancer Act Amendments of 1978

Public Law 95-622 42 U.S.C. §§ 281-286

Through the Community Mental Health Centers Act the National Cancer act was amended to emphasize education and demonstration programs in cancer treatment and prevention; the act stipulated that the Institute devote more resources to prevention, focusing particularly on environmental, dietary, and occupational cancer causes.

Key Sections of Act--Toxics Focus

sec. 402	Authorized the NCI to expand and intensify its research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens.
sec. 407(a)(1)	The membership of the National Cancer Advisory Board was expanded from 23 to 29. Not more than five of the appointed members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors).

The National Cancer Act Amendments of 1980

Public Law 96-538 42 U.S.C. §§ 281-286

The Health Programs Extension Act of 1980 extended the National Cancer Institute authorization for three years.

TOXICS-RELATED ACTIVITIES*

The broad goals of NCI's toxics programs are to identify environmental carcinogens, to establish and measure the relation between carcinogens and the incidence of cancer, and to prevent cancer through educational and other programs. NCI is a major source of information on cancer incidence and mortality for researchers studying environmental carcinogens. Through its programs, the NCI seeks to develop knowledge on the causes of cancer from epidemiological studies correlating exposure amounts with the incidence of cancer; from animal-human correlations developed by comparing results of studies in experimental animals with epidemiological studies; from comparative studies in various species on carcinogen metabolism, pharmacokinetics, carcinogen-DNA adduct formation and DNA repair; and from studies of host factors leading to increased or decreased susceptibility to environmental carcinogens.

The Institute's programs touch on a broad range of cancer-related areas of study: the susceptibility of fetuses and children to environmental agents; cancer mapping, or the relation of cancer incidence to potential environmental causes; correlation studies linking localized mortality rates with corresponding environmental data; the connection of cancer incidence to occupation; and special studies to determine the factors at work in communities with particularly high or particularly low rates of cancer. In addition, the NCI conducts programs studying the relationships between synthetic estrogens and breast cancer, artificial sweeteners and bladder cancer, halogenated hydrocarbons in drinking water and increased rates of cancer, and occupational hazards and cancer.

In addition, the NCI provides advice and staff expertise on environmental carcinogenesis to other government agencies. It provides advice in an informal way to agencies by keeping their staffs apprised of new information and developments in the area of carcinogenesis research. The NCI also provides input to NIOSH on occupational and environmental carcinogenesis through members of the Environmental Epidemiology Branch of the Field Studies and Statistics Program. Other NCI staff members serve on panels and committees organized by regulatory and other agencies. For example, NCI staff are members of the Interagency Testing Committee organized to evaluate chemicals covered by the Toxic Substances Control Act. Staff from the NCI also serve as members of the Task Force on Environmental Cancer and Heart and Lung Disease and on the DHHS Committee to Coordinate Environmental and Related Programs. The latter committee was established by the Assistant Secretary for Health as a multi-agency group to exchange information on environmental health, toxicology and related programs. In addition to representatives from each agency in HHS which supports or conducts these types of programs, there are liaison representatives from CPSC, EPA, OSHA, CEQ, Library of Congress, Department of Energy, National Oceanographic and Atmospheric Administration, Department of Defense and the NSF. The Interagency Collaborative Group on Environmental Carcinogenesis is an informational committee, chaired by a representative from NCI, which serves as a forum for exchanging information among its member organizations: NCI, NIEHS, FDA, USDA, and CEQ, NOAA, NASA, the Department of Transportation, NSF and others involved in environmental carcinogenesis research. The NCI is also involved in developing collaborative activities related to environmental carcinogenesis. The cooperative projects on environmental/occupational carcinogenesis are with other Federal agencies (NIEHS, EPA, NIOSH, and OSHA), State agencies and other institutions. The NCI/EPA and CNI/NIOSH collaborative programs on environmental and occupational carcinogenesis are managed jointly by co-project officers from NCI and the EPA or NIOSH.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omission to the attention of the Office of Pesticides and Toxic Substances, Chemical Coordination Staff.

In 1981, the carcinogenesis testing program was transferred to the National Institute of Environmental Health Sciences (NIEHS) from NCI, and action which provides for direct management by the National Toxicology Program of the NIH components of the program. Nevertheless, the NCI maintains a significant level of involvement in the carcinogenesis testing program by nominating chemicals for testing in the bioassay program and by membership on the NTP Executive Committee, which selects the chemicals to be tested.

The Cancer Control Program

The Cancer Control Program, established in 1972, has numerous activities aimed at controlling the occurrence and impact of the major causes of cancer. Educational programs have been developed for health professions, the medical community, and the general public. The Cancer Control Program conducts conferences for analyzing and determining the scientific basis of recommendations for cancer screening programs and provides research grants to individuals or institutions studying methods of cancer control. Under the Cancer Control Program, an information network on the diagnosis and treatment of specific types of cancer is being developed. This network will link hospitals and physicians at the community level with selected primary hospitals.

Cancer control research, defined as the reduction of cancer incidence, morbidity and mortality through an orderly sequence from research on interventions and their impact in defined populations to their broad, systematic application, is the mission of DRCCA. Cancer control research activities and interventions are designed to promote the application of knowledge gained through basic research and technological advances to the problems of cancer prevention and control. DRCCA facilitates and supports research to reduce the incidence of cancer from all risk factors (occupational/environmental, behavioral/lifestyle, heredity/genetic) in populations determined to be high-risk or high-need and in the public-at-large. Interdisciplinary efforts, drawing on the fields of occupational health and medicine, education, behavioral-social sciences, and communication/information sciences interact to develop, implement and evaluate programs aimed at modifying the risk for cancer in populations.

Selected examples from the Program areas of DRCCA:
1. Smoking, Tobacco and Cancer Program

The National Cancer Institute's (NCI) Smoking, Tobacco, and Cancer Program (STCP) serves as the focal point for NCI's research, disease prevention, and health promotion activities related to smoking and cancer. Although responsibility for programmatic research and control activities rests with several of NCI's divisions and offices, central coordination of the STCP is provided by the Office of the Director, DRCCA, where the broader emphasis on cancer control research is administered. The STCP's overall goals are to identify cancer risks associated with smoking and tobacco use and to develop strategies for prevention and cessation of tobacco-use behavior. Current activities include community and school-based intervention and education programs aimed at deterring risk of smoking behavior in children and adolescents, the development of cessation programs targeted toward high risk subgroups, studies aimed at understanding the bio-behavioral dependence on smoking and tobacco use, epidemiological studies to assess health effects due to changing smoking and tobacco habits, toxicological studies to determine promoting and carcinogenic effects of constituents in both the particulate and gaseous phases of cigarettes, and biological and epidemiological studies to identify individuals and groups at unusually high risk for the development of cancer.

Some current areas of research of particular relevance to risk assessment and reduction include:

- Studies to develop, implement, and evaluate smoking prevention programs for youth and adolescents.
- Studies to develop, implement, and evaluate formal and informal self-help approaches for smoking cessation.
- Studies focused on the prevention implications of understanding the psychosocial and situational variables that influence smoking and non-smoking behavior among youth.
- Studies to develop effective methods for modifying smoking behavior among special at-risk populations.
- Studies to determine stimulation and stress levels which might predispose individuals to smoke.

Future risk-related research to be supported through the STCP will focus primarily upon risk reduction activities. As a result of a number of consensus meetings held at NCI during the winter and spring of 1983, several RFAs have been developed, and others planned, which will: (1) continue and expand the NCI STCP's interest in longitudinal school-based smoking prevention studies and development of self-help strategies for the prevention and cessation of smoking; (2) initiate studies focused on longitudinal evaluation of physician and dentist interventions, evaluation of smoking prevention and cessation activities using the mass media; and (3) conduct smoking prevention and cessation research among Hispanic and Black populations.

2. Cancer Prevention Program
   A. The Occupational Cancer Branch:
   All projects in occupational cancer control involve the assessment of risk factors in occupationally defined

populations and the evaluation of approaches to the modification of such risk factors. At present, studies are underway to reduce risks in the following areas:

Population	Target Site of Cancer	Grant No.
Painters	Multiple	34919
Coke Oven	Lung	34916
Rubber	Bladder; Multiple	34912
Auto Assembly	Multiple	34914
Chemical Workers	Multiple	34917
Insulation Production (Asbestos)	Lung; Mesothelioma; Colon	27582
Pattern Makers	Colo-rectal	27582
Dye Workers	Bladder	27582

Additionally, program planning is underway to inventory existing information on workers at high risk of cancer, to develop criteria for establishing future program priorities and to propose priorities for future program activities. Each of the activities involves risk assessment.

B. The Cancer Detection Branch supports the:
(1) Human Radiation Carcinogenesis Study of the three well-defined irradiated populations and their controls. These individuals have been studied longitudinally over 15 years for reported morbidity and mortality. The effects of irradiation earlier in life on subsequent health remain evident in this population. The project aims to continue longitudinal surveillance, quantify the cancer risks and screen these high-risk populations for cancer; and

(2) Study of Predictive Value of the Wolfe Classification in Breast Cancer Detection Demonstration Projects (BCDDPs). The focus of the study is the relationship of the Wolfe classification of mammographic parenchymal patterns to the risk of developing breast cancer and the relation of the patterns to other risk factors for breast cancer. Conducted in the case-control mode, this long term study aims to provide scientific evidence for the predictability of the Wolfe classification scheme.

3. The Cancer Control Science Program

The Health Promotion Sciences Branch supports research relative to health promotion/disease prevention efforts, utilizing behavioral, social, educational or communication interventions to alter lifestyle practices so as to prevent the carcinogenic effects of known risk factors. Examples of peer review grant supported projects include:

Behavioral Aspects of Cancer Incidence and Mortality (34457) examines overall relationships between cancer and demographic characteristics, relating risk factors and mortality or incidence and multivariate multiple logistic regression. This prospective, descriptive study in a defined population, Alameda County, California, has the potential for generating hypotheses to be tested regarding the relationship of behavioral factors, personal health habits, and psychosocial functioning on the occurrence of cancers of all types and on total cancer deaths.

Psychosocial Stress and Cancer Risk: A Prospective Study (34618) examines relationships between cancer and stressors in a population of workers with 30 years' exposure to asbestos. The project capitalizes on a unique opportunity to test hypotheses about the relationship between psychological factors, including life stressors, and cancer in a population at high risk of developing cancer and other diseases within the next five years.

Primary Prevention of Cancer in Childhood (25521) is a controlled clinical trial of 1200 students, initially ages nine and ten, to identify major cancer and other disease risk factors, to reduce elevated risk status through planned interventions and to reinforce and maintain reduced risk status. This ongoing program is expected to make significant contributions to nutrition, cancer education and the modification of behaviors which increase risk factors.

The Diet, Nutrition, and Cancer Program

The Diet, Nutrition and Cancer Program (DNCP), established in 1974, coordinates efforts within the NCI to develop and disseminate information about the role of diet and nutrition in the etiology and prevention of cancer and in the treatment, long term management, and rehabilitation of the cancer patient, and to coordinate NCI nutrition activities with those of other organizations. Studies of dietary manipulation aimed at reducing cancer incidence have been supported in animals and are being initiated in humans.

In 1981, the DNCP was placed organizationally in the Division of Resources, Centers, and Community Activities of the NCI, where efforts continue toward developing an integrated and coordinated nutrition program within the Institute. However, each division retains responsibility for funding and day-to-day management of specific nutrition projects. For example, DCCP is placing considerable emphasis on studies in the area of diet, nutrition and cancer, focusing on inhibitors of carcinogenesis which are present as normal constituents of foodstuffs.

The Cancer Centers Program

The Cancer Centers Program was founded in 1961 for the development and dissemination of information on the most effective methods of cancer prevention, diagnosis, treatment, and rehabilitation. The emphasis of the program is on providing financial support to institutions engaged in multidisciplinary research. The Program seeks to attract physicans and scientists of diverse background in order to develop a broad base of information cancer control activities.

Supporting Programs

The major objectives of the Carcinogenesis Intramural Program (DCCP) are to conduct and support research to identify the determinants of cancer in man, to understand their mechanisms of action and to develop and evaluate measures that will arrest, reverse, or otherwise interfere with the initiation or progression of the cancer process. These objectives include the development of optimum procedures for culturing epithelial cells from various animal and human tissues and the evaluation of the effects of environmental carcinogens and co-carcinogens on those cells; the development of sensitive procedures to detect the covalent binding of chemical carcinogens to DNA of individuals potentially exposed to such substances; to correlate individual differences in metabolism of environmental carcinogens with susceptibility to tumor induction; and identification, isolation and characterization of new tumor inhibitory substances and the synthesis and evaluation of analogs of known inhibitors.

The programs at the Frederick Cancer Research Facility pursue a wide variety of fundamental studies in biological and chemical carcinogenesis with the objective of providing information applicable to the understanding and control of cancer in man. Studies are being performed on the interaction between chemical structure and carcinogenic activity, and on the biochemical and molecular mechanisms of action of chemical carcinogens.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

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Public Health Service
National Institutes of Health
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FTS: 629-3345

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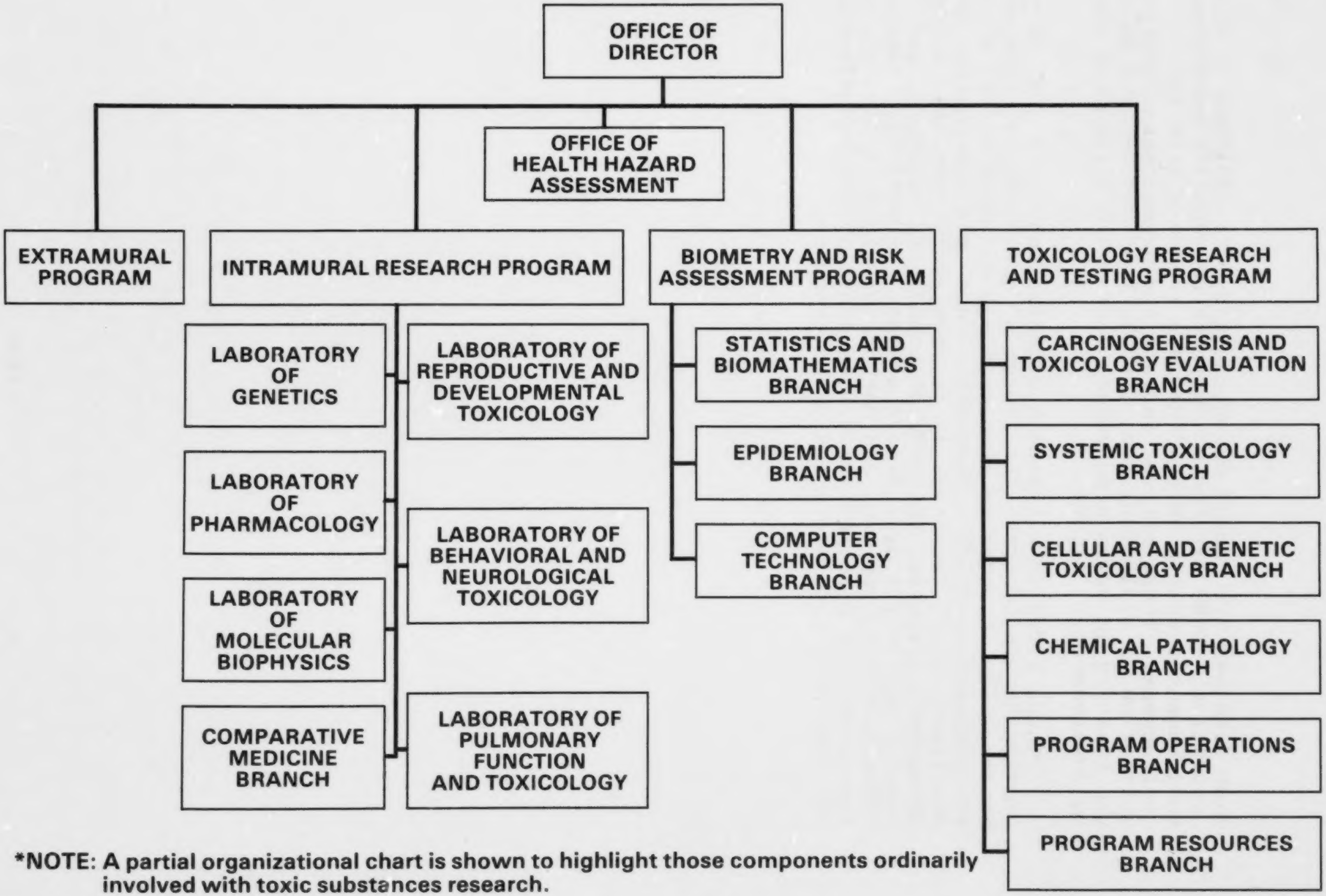
The National Institute of Environmental Health Sciences (NIEHS) has the broadest responsibility among Federal agencies for the support of biomedical research and the training of research manpower relating to the effects of chemical, physical, and biological environmental agents on human health. The goal of NIEHS is to provide the scientific information base, advanced scientific methodology, and trained scientific manpower to reach an understanding of the total impact of environmental factors on human health, so that the health of the American people can be protected and environmentally-induced disease can be prevented.

NIEHS pursues its mission by supporting research training in environmental toxicology, environmental pathology, environmental mutagenesis, and environmental epidemiology, and by funding basic and applied research on the consequences of the exposure of humans and other biological systems to potentially toxic or harmful agents in the environment. In its research, NIEHS attempts to learn: (1) how and where potentially harmful environmental agents are released into the environment; (2) how they affect humans and other biological systems in the environment; (3) the extent of exposure of various population groups (particularly sensitive populations) to these agents; (4) the effects these agents cause, both separately and in combination with other environmental agents; (5) what happens in biological systems after exposure to hazardous agents; and (6) what diseases are caused or aggravated. In addition to these activities, NIEHS carries out efforts to identify hazardous environmental agents before they are released into the environment. These efforts include the development, testing, and validation of biological test systems that can be used to predict the toxicity in human populations that would occur from exposure to environmental factors.

Thus, NIEHS is a research organization whose goal is to provide knowledge about the impact of environmental factors on human health in order to protect the public health and to prevent environmentally-related diseases. Once this information is developed, NIEHS transmits it to regulatory agencies, other Government agencies, the medical community, industry, and the general public for appropriate action. Accordingly, results of NIEHS research, testing, and methods development form the basis for prevention programs for environmentally-induced diseases and for action by regulatory and other agencies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
ORGANIZATIONAL CHART*


OFFICE OF DIRECTOR
OFFICE OF HEALTH HAZARD ASSESSMENT
EXTRAMURAL PROGRAM
INTRAMURAL RESEARCH PROGRAM
LABORATORY OF GENETICS
LABORATORY OF REPRODUCTIVE AND DEVELOPMENTAL TOXICOLOGY
LABORATORY OF PHARMACOLOGY
LABORATORY OF BEHAVIORAL AND NEUROLOGICAL TOXICOLOGY
LABORATORY OF MOLECULAR BIOPHYSICS
COMPARATIVE MEDICINE BRANCH
LABORATORY OF PULMONARY FUNCTION AND TOXICOLOGY
BIOMETRY AND RISK ASSESSMENT PROGRAM
STATISTICS AND BIOMATHEMATICS BRANCH
EPIDEMIOLOGY BRANCH
COMPUTER TECHNOLOGY BRANCH
TOXICOLOGY RESEARCH AND TESTING PROGRAM
CARCINOGENESIS AND TOXICOLOGY EVALUATION BRANCH
SYSTEMIC TOXICOLOGY BRANCH
CELLULAR AND GENETIC TOXICOLOGY BRANCH
CHEMICAL PATHOLOGY BRANCH
PROGRAM OPERATIONS BRANCH
PROGRAM RESOURCES BRANCH

*NOTE: A partial organizational chart is shown to highlight those components ordinarily involved with toxic substances research.

ORGANIZATION*

OFFICE OF HEALTH HAZARD ASSESSMENT

- Plans, develops, and directs the Institute's health hazard assessment activities.
- Identifies environmental and technological developments having the potential for adversely affecting human health.
- Evaluates the health significance of these developments.
- Recommends Institute policy and program action based upon these assessments.
- Serves as the Institute focal point for functions of this kind, including managing its functions as a World Health Organization Collaborating Center.

EXTRAMURAL PROGRAM

- Plans, directs, and evaluates the Institute's grant program, which supports research and research training in environmental health.
- Develops program priorities and recommends funding levels to assure maximum use of available resources in attainment of Institute objectives.
- Prepares reports for and provides advice to the Institute Director, staff, and advisory groups to assist them in carrying out their responsibilities.
- Represents the Institute Director in the development and implementation of grant policy.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

INTRAMURAL RESEARCH PROGRAM

o Plans and conducts the Institute's basic laboratory research program to ensure maximum utilizaton of available resources in the attainment of Institute objectives.

o Evaluates research efforts and establishes program priorities.

p Integrates ongoing and new research activities into the program structure.

o Collaborates with other Institute and NIH programs and maintains awareness of national research efforts in program areas.

o Provides advice to the Institute Director and staff on matters of scientific interest.

Laboratory of Genetics

o Studies the structure, function, and regulation of genes of prokaryotic and eukaryotic organisms with emphasis on understanding the impact mutational events have on the fitness of organisms.

o Conducts studies in prokaryotic and eukaryotic systems intended to improve the basic understanding of mutation mechanisms, mutation repair, and mutation avoidance processes.

o Develops and validates *in vitro* and *in vivo* mutation induction systems and models to detect and quantitate mutagenic activity of environmental agents.

o Studies amounts and types of genetic variation in natural populations and develops systems and models to facilitate extrapolation from experimental systems to humans.

o Advises the staff of NIEHS and other entities on issues pertaining to genetics.

Laboratory of Pharmacology

- Plans and conducts studies on the biological effects of environmental factors.
- Studies species differences in metabolism of, and dose- and time-response relations for, the actions of selected environmental hazards.
- Studies accumulation, distribution, and disposition of environmental chemicals in a variety of animal species.
- Studies the interactions between toxic chemicals and between these and other normal body constituents or drugs to elucidate those interactions which may be adversely synergistic.
- Conducts selected studies in marine biology research, and coordinates and advises Institute staff and personnel of other organizations on marine biology research applicable to effects of environmental pollutants on human health.

Laboratory of Molecular Biophysics

- Plans and conducts studies to develop, improve, and utilize spectroscopic methods (nuclear magnetic resonance, electron spin resonance, and mass spectrometry) to characterize and measure the molecular interactions that occur between environmental agents and biological systems.
- Plans and conducts physical organic and bioorganic chemical studies of environmental agents, biological materials, and their conversion products with emphasis on elucidation of chemical mechanisms in biological damage.
- Develops, improves, and utilizes analytical methodology for specified agents and problems in collaborative research with other NIEHS laboratory and research programs.

Comparative Medicine Branch

- Manages a program for environmental animal procurement, housing, and utilization within the Institute.
- Develops, refines, and advises Institute scientists and programs of appropriate animal models for use in Institute research programs.
- Maintains collaborative laboratories in microbiology, experimental surgery, laboratory animal medicine, and mammalian reproduction.
- Plans and conducts research appropriate to these laboratory functions.

Laboratory of Reproductive and Developmental Toxicology

- Conducts research directed toward the understanding of mechanisms of reproductive, endocrinologic, and developmental toxicity produced by exposure to environmental agents.
- Determines mechanisms of teratogenesis by using *in vivo* and *in vitro* techniques to develop more rapid and economical laboratory methods to predict teratogenesis.
- Assesses environmental agents for their teratogenic potential.
- Determines the molecular mechanisms underlying cellular differentiation.
- Studies the molecular basis and determines the effects of environmental agents on the endocrine function of the reproductive system.
- Analyzes the effects of prenatal exposure to hormonally active environmental agents on the development of reproductive tract function.
- Determines the possible gestational origin of subtle toxic effects which do not become apparent until later in life.
- Defines the effects of environmental agents on oogenesis and spermatogenesis.

- Develops preclinical indicators of reproductive, endocrinologic, and developmental toxicity using in vitro cells and tissues, lower animals, and biochemical test systems.

Laboratory of Behavioral and Neurological Toxicology

- Plans, conducts, and coordinates studies on behavioral and neurological effects of environmental chemicals and stressors to develop better tests for these effects, as well as to use behavioral and neurological indices as early warning systems for environmentally-induced diseases.
- Evaluates behavioral and neurologic toxicity of selected chemicals, including the effects of chronic microwave exposure in developing animals.
- Studies neurophysiological effects of chemicals and high noise levels on cellular mechanisms of electrical impulse propagation and processing.
- Collaborates with other Institute programs to develop broad interdisciplinary programs for evaluating subtle effects of chemicals on the central and peripheral nervous systems.
- Serves as a national focus for activities in this research area, maintaining liaison and collaboration with other laboratories investigating the effects of chemicals on behavior.

Laboratory of Pulmonary Function and Toxicology

- Develops a central focus at NIEHS for research on effects of environmental chemicals and stressors on the lung.
- Conducts studies to develop new methods for assessing and detecting adverse effects of chemicals on the lung.
- Plans and conducts studies to elucidate the mechanisms by which chemicals and other stressors cause adverse effects on the lung.
- Investigates the nature of adverse effects of selected chemicals and mixtures of chemicals on the lung, and attempts to understand species differences in lung damage by selected chemicals.

BIOMETRY AND RISK ASSESSMENT PROGRAM

- Plans and conducts basic and applied environmental health oriented research in the areas of risk assessment, statistics, biomathematics, and epidemiology.
- Collaborates with scientists involved in the Toxicology Research and Testing Program, assuming responsibility for data management and statistical analysis.
- Provides statistical, mathematical, data processing, and computer engineering support to other program areas within the Institute.
- Assists the Office of the Director in addressing specific health issues that bear on the welfare of the general public.

Statistics and Biomathematics Branch

- Conducts a broad research effort ranging from statistical analysis to biomathematical modeling aimed at developing new or improved methods for qualitative and quantitative risk estimation, particularly in the areas of carcinogenesis, mutagenesis, teratogenesis, and reproduction.
- Maintains an active research program in statistical methodology development relevant to design and analysis issues arising in laboratory experimentation, with special emphasis on toxicological screening studies.
- Provides a comprehensive consulting service for the Epidemiology Branch, the Toxicology Research and Testing Program, and the Intramural Research Program.

Epidemiology Branch

- Initiates field studies of human diseases, particularly those of a chronic nature, that are suspected of having an environmental component in their etiologies.
- Investigates the effects of environmental toxins on fetal and child development.
- Conducts basic and applied research on the development and use of laboratory methods to monitor human populations for environmental exposures and their effects.

Computer Technology Branch

- Operates and maintains the Institute's computer systems and the network of terminals connected to the various computers at NIH/DCRT.
- Provides programming consultation services, including software systems development, to Institute personnel.
- Maintains an active computer engineering group which provides continuing support to laboratory research activities in various branches.
- Provides systems analysis and project managment support to both Institute and NTP system development projects.

TOXICOLOGY RESEARCH AND TESTING PROGRAM

- Plans and conducts research to develop, validate, and evaluate methods for characterizing the toxicology of chemical compounds and other environmental agents.
- Plans and conducts a program of research and testing, including short term screening and long term animal toxicology and carcinogenesis studies, to establish the toxicity of chemical compounds and other environmental agents.
- Collaborates with chemical toxicology test development and testing programs of other Government agencies.
- Disseminates results of tests, test development, and test validation efforts to interested members of the scientific community and to Federal regulatory agencies.

Carcinogenesis and Toxicology Evaluation Branch

- Conducts research intended to develop and validate improved toxicity testing methodologies, establish short term and screening test systems, and improve interpretation of long term toxicology and carcinogenesis results.
- Collaborates as toxicology experts with other scientific staff in the program involved in test development and validation and test protocol preparation.

- o Monitors testing program to assure the quality and validity of the toxicology components of the tests.

Systemic Toxicology Branch

- o Conducts research to improve test protocols, to develop new tests, and to improve interpretation of test results related to the toxicity of chemicals on a variety of organs, tissues, and cells.
- o Collaborates as specific experts in fields such as toxicology, immunology, pharmacokinetics, and physiology with other scientific staff of the program involved in test development and validation and test protocol preparation.

Cellular and Genetic Toxicology Branch

- o Plans, develops, and implements a combined intramural and collaborative research program.
- o Studies the genetic and related effects which result from exposure to environmental agents.
- o Develops, standardizes, and applies short term *in vitro* test systems in which large numbers of chemicals can be screened for cellular and genetic toxicity.
- o Develops and standardizes *in vitro* and *in vivo* test systems as models for carcinogenesis and mutagenesis that provide for extrapolation to humans.
- o Develops and utilizes computer data files for storage, retrieval, and analysis of genetic toxicity test data.

Chemical Pathology Branch

- o Conducts research using pathologic methodology into the induction of morphologic changes induced by toxic environmental agents.
- o Studies and interprets the results of tests using pathologic methodology.
- o Collaborates as pathology experts with other scientific staff in the program involved in test development and validation and test protocol preparation.

- Monitors testing program to assure the quality and validity of pathology components of the test.

Program Operations Branch

- Maintains continual planning, oversight, coordination, and surveillance of toxicology testing activities.

- Undertakes scientific and technical monitoring of test laboratories.

- Assembles, maintains, and utilizes scientific, management, and financial data bases related to the testing activities of the program.

- Maintains an interface between research staff and contracts management staff to ensure proper conduct of tests and reporting of bioassay and related toxicology results.

Program Resources Branch

- Provides a range of special support resources for toxicology and carcinogenesis testing and test development activities.

- Assures acquisition and quality control of test animals.

- Provides for acquisition, quality control, and standardization of test chemicals.

- Monitors laboratory safety, chemistry, and animal care practices.

STATUTORY AUTHORITY

Public Health Service Act

Public Law 78-410 42 U.S.C. § 201

The authority under which the NIEHS supports and conducts its research in Section 301 of the Public Health Service Act, which gives the Secretary of HHS broad powers to conduct and support research relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.

Key Sections of Act--Toxics Focus

sec. 301(a)	Authorizes Surgeon General to conduct and "promote the coordination of research investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams."
sec. 301(b)	Authorizes the Surgeon General to make available any research facilities, public authorities, health officials, or scientists engaged in related fields of study.

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NATIONAL INSTITUTE
FOR OCCUPATIONAL SAFETY AND HEALTH

Department of Health and Human Services
Public Health Services
Centers for Disease Control

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Laboratories

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4676 Columbia Parkway
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55 Ridge Avenue
Cincinnati, Ohio 45213

Appalachian Laboratory for
Occupational Safety and Health
944 Chestnut Ridge Road
Morgantown, West Virginia 26505

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Introduction

The National Institute for Occupational Safety and Health (NIOSH), created by the Occupational Safety and Health Act of 1970, is the principal Federal agency involved in research to eliminate on-the-job hazards to the health and safety of the Nation's workforce.

Before 1970, investigators could enter workplaces only at the request of employees or State and local health departments. The 1970 Act gave the Institute this access, as well as specific responsibility for research, for recommending standards to the Occupational Safety and Health Administration, and for training professionals in the field of occupational safety and health. The Federal Mine Safety and Health Amendments Act of 1977 confers responsibility to conduct Health Hazard Evaluations in mines, research related to miner health, and to approve dust samplers and respirators. This legislation also gives NIOSH the authority to recommend standards for health in mines.

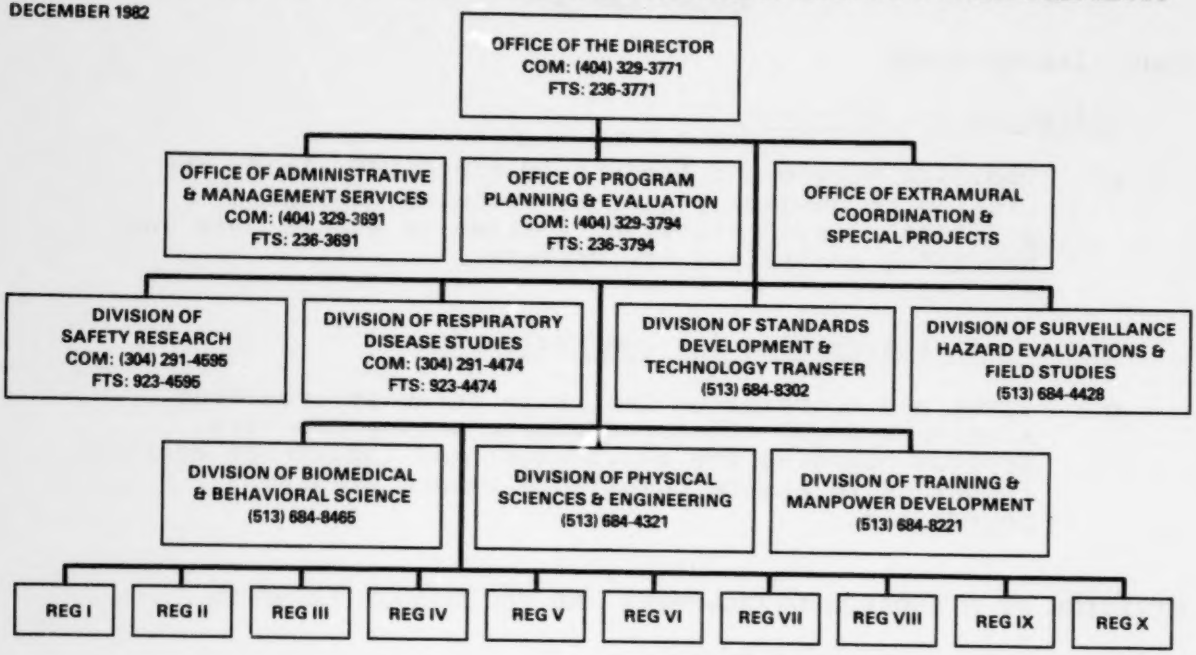
Since 1973, NIOSH has been administered by the Centers for Disease Control and is headquartered in Atlanta, Georgia. Major NIOSH laboratory facilities are located in Cincinnati, Ohio, and Morgantown, West Virginia. In addition, personnel are stationed in the ten DHHS regional offices.

At the Institute's main laboratories in Cincinnati, studies include the effects of exposure to hazardous substances in the workplace, as well as the psychological, motivational, and behavioral factors involved in occupational safety and health. Staff in Cincinnati are also responsible for the preparation and update of the Criteria documents and other information documents. These documents, which utilize research performed in NIOSH laboratories or under contract, serve as the basis for standards to be promulgated by the Occupational Safety and Health Administration or by the Mine Safety and Health Administration and for assessment of hazards and recommendations for worker protection.

At its second laboratory, in Morgantown, West Virginia, NIOSH conducts studies in respiratory disease and mining health. In addition, the Institute's safety research and respirator certification programs are located there.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

DECEMBER 1982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OFFICE OF ADMINISTRATIVE & MANAGEMENT SERVICES COM: (404) 329-3691 FTS: 236-3691
OFFICE OF PROGRAM PLANNING & EVALUATION COM: (404) 329-3794 FTS: 236-3794
OFFICE OF EXTRAMURAL COORDINATION & SPECIAL PROJECTS
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DIVISION OF RESPIRATORY DISEASE STUDIES COM: (304) 291-4474 FTS: 923-4474
DIVISION OF STANDARDS DEVELOPMENT & TECHNOLOGY TRANSFER (513) 684-8302
DIVISION OF SURVEILLANCE HAZARD EVALUATIONS & FIELD STUDIES (513) 684-4428
DIVISION OF BIOMEDICAL & BEHAVIORAL SCIENCE (513) 684-8465
DIVISION OF PHYSICAL SCIENCES & ENGINEERING (513) 684-4321
DIVISION OF TRAINING & MANPOWER DEVELOPMENT (513) 684-8221
REG I
REG II
REG III
REG IV
REG V
REG VI
REG VII
REG VIII
REG IX
REG X

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AND HEALTH
4676 COLUMBIA PARKWAY
CINCINNATI, OHIO 45226

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AND HEALTH
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MORGANTOWN FACILITY
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AND HEALTH
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FTS: 758-3491

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1961 STOUT, FOB, ROOM 1185
DENVER, COLORADO 80294
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FTS: 327-6382

DHHS, REGION IX
50 UNITED NATIONS PLAZA, ROOM 303
SAN FRANCISCO, CALIFORNIA 94102
TEL.: 415/556-3781
FTS: 556-3781

DHHS, REGION X
2901 THIRD AVENUE, MS/402
SEATTLE, WASHINGTON 98121
TEL.: 206/442-0530
FTS: 399-0530

ORGANIZATION*

NIOSH HEADQUARTERS

Office of the Director

- Provides management leadership for NIOSH; leads the mission to conduct research, training, technical assistance, and related activities to ensure safe and healthful conditions for workers.

Office of Program Planning and Evaluation

- Plans and coordinates Institute strategy regarding mission and objectives; conducts policy analyses, program planning and evaluation; and implements control functions to ensure compliance toward program objectives.

DIVISION OF STANDARDS DEVELOPMENT AND TECHNOLOGY TRANSFER

Document Development Branch

- Provides the scientific effort necessary to develop criteria for occupational health standards.
- Coordinates the development and final approval of occupational health criteria and standards documents in cooperation with the U.S. Department of Labor.

Priorities Research Analysis Branch

- Analyzes information on the exposure of workers to safety and health hazards.
- Prepares and periodically revises a priority list of substances and industries for which activity is warranted, either for future research or for new recommendations.
- Prepares and annually revises the legislatively mandated Registry of Toxic Effects of Chemical Substances (RTECS).

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*NOTE: Only those offices which deal with toxics effects or toxics-related issues are developed in this section.

- Conducts Special Occupational Hazards Reviews of potential workplace hazards when new evidence of a particular hazard is received, and prepares recommended emergency temporary standards as appropriate.

- Assists the Mine Safety and Health Administration, Department of Labor, in the development of draft regulations.

Technical Information Branch

- Receives, stores, develops and disseminates technical information on occupational safety and health hazards.

- Develops publications promoting safe and healthful working conditions.

DIVISION OF TRAINING AND MANPOWER DEVELOPMENT

- Conducts short-term training programs in occupational safety and health, including programs in toxicology and hazardous waste.

DIVISION OF SURVEILLANCE, HAZARD EVALUATIONS, AND FIELD STUDIES

Hazard Evaluation and Technical Assistance Branch

- Conducts the legislatively mandated Health Hazard Evaluation program.

- Provides medical, technical, and consultative assistance to Federal, State, and local agencies, labor, industry, and others to control occupational health hazards and to prevent related trauma and diseases.

Industry-wide Studies Branch

- Conducts epidemiological industry-wide field studies to determine the incidence and prevalence of acute and chronic disease in the working population and their offspring.

Surveillance Branch

- Develops and maintains a national surveillance system for the early detection and continuous assessment of the magnitude and extent of occupational illness and of exposures to hazardous agents.

DIVISION OF BIOMEDICAL AND BEHAVIORAL SCIENCE

- Conducts laboratory research for the development of criteria for standards in the areas of toxicology, behavioral science, physiology, ergonomics, and the effects of physical agents.

Experimental Toxicology Branch

- Performs laboratory research to develop critical toxicity data on materials found in the occupational environment.
- Investigates the mechanisms of occupational disease.
- Contributes to the development of occupational health criteria for the recommendation of standards.

DIVISION OF PHYSICAL SCIENCES AND ENGINEERING

Engineering Control Technology Branch

- Plans and conducts laboratory and worksite research to assess and develop engineering control techniques to prevent worker exposure to toxic substances and harmful physical agents.

Methods Research Branch

- Conducts research to develop new sampling and analytical methods for use in measuring potential contaminants in the workplace.

Measurements Research Support Branch

- Provides sampling consultation and analytical support for Health Hazard Evaluations, engineering control systems, and other NIOSH field research.

DIVISION OF RESPIRATORY DISEASE STUDIES

- Conducts clinical and epidemiological research on occupational respiratory disease.

- Provides legislatively mandated medical and autopsy services under the Federal Mine Safety and Health Act of 1977.

- Conducts medical research to fulfill the Institute's responsibilities under the Federal Mine Safety and Health Act of 1977.

- Conducts Health Hazard Evaluations for mines.

DIVISION OF SAFETY RESEARCH

Testing and Certification Branch

- Tests and certifies respirators; tests other personal protective devices and occupational hazard measuring devices.

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Office of Administrative and Management Services	Com: (404) 329-3691 FTS: 236-3691	Atlanta, Ga.
Office of Program Planning and Evaluation	Com: (404) 329-3794 FTS: 236-3794	Atlanta, GA.
Office of Extramural Coordination and Special Projects	Com: (301) 496-6723 FTS: 496-6723	Bethesda, MD
Division of Standards Development and Technology Transfer	Com: (513) 684-8302 FTS: 684-8302	Cincinnati, Ohio
Division of Training and Manpower Development	Com: (513) 684-8221 FTS: 684-8221	Cincinnati, Ohio
Division of Surveillance, Hazard Evaluations, and Field Studies	Com: (513) 684-4428 FTS: 684-8221	Cincinnati, Ohio
Division of Biomedical and Behavioral Science	Com: (513) 684-8465 FTS: 684-8465	Cincinnati, Ohio
Division of Physical Sciences and Engineering	Com: (513) 684-4321 FTS: 684-4321	Cincinnati, Ohio
Division of Respiratory Disease Studies	Com: (304) 291-4474 FTS: 923-4474	Morgantown, WV
Division of Safety Research FTS: 923-4595	Com: (304) 291-4595	Morgantown, WV
Public Information Officer FTS: 236-3061	Com: (404) 329-3061	Atlanta, Ga.
Legislative Officer FTS: 236-3061	Com: (404) 329-3061	Atlanta, Ga.
Clearinghouse for Occupational Safety and Health Information (Technical Information Branch)	Com: (513) 684-8326 FTS: 684-8326	Cincinnati, Ohio

REGIONAL OFFICES

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NIOSH DHHS, Region II	Federal Bldg. 26 Federal Plaza, Room 3337 New York, NY 10278	(212) 264-2485/8 FTS: 264-2485
NIOSH DDHS, Region III	P.O. Box 13716 Philadelphia, PA 19101	(215) 596-6716 FTS: 596-6716
NIOSH DHHS, Region IV	101 Marietta Tower Suite 1007 Atlanta, Ga. 30323	(404) 221-2396 FTS: 242-2313
NIOSH DHHS, Region V	300 South Wacker Drive 26th Floor Chicago, IL 60606	(312) 886-3651 FTS: 886-3651
NIOSH DHHS, Region VI	1200 Main Tower Bldg. Room 1835 Dallas, TX 75202	(214) 767-3916 FTS: 729-3916
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NIOSH DHHS, Region VIII	1861 Stout, FOB, Room Denver, CO 80294	(303) 873-6382 FTS: 327-6382
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NIOSH DHHS, Region X	2901 Third Avenue, MS/402 Seattle, WA 98121	(206) 442-0530 FTS: 399-0530

Current NIOSH Working Groups

Working Group on the Control of Occupational Lung Disease

MEMBERS	MAIL STOP	TELEPHONE
John Hankinson (Chairperson)	ALOSH - 256	923-4755
Tom Hodous	ALOSH - 240	923-4223
Frank Hearl	ALOSH - 120	923-4221
Frank Green	ALOSH - 240	923-4581
Bob Mullan	TAFT - F-2	684-3269
Jim Melius	RIDGE - R-9	684-4328
Bill Moorman	TAFT - C-23	684-4275
Lawrence Doemeny	RIDGE - R-1	684-4322
John Gamble	ALOSH - 224	923-4476
Martin Sepulveda	ALOSH - 240	923-4223

Working Group on the Control of Musculoskeletal Injuries

Vern Putz-Anderson (Chairperson)	TAFT - C-24	684-8383
Roger Jensen	ALOSH - 124	923-7454
Roger Nelson	ALOSH - C-14	496-7807
Lee Sanderson	ALOSH - S-105	923-7576
Shiro Tanaka	Cincinnati - F-6	684-2352
Donald Badger	TAFT - C-24	684-8286

Working Group on the Control of Occupational Cancers

William Halperin (Chairperson)	RIDGE - F-8	684-2694
Richard Niemeier	TAFT - C-23	684-8394
David Groth	TAFT - C-26	684-8361
Todd Frazier	Cincinnati - F-2	684-2641
Paul Caplan	RIDGE - R-5	684-4224
James Jones	RIDGE - R-5	684-4295
Francis H. Green	ALOSH - 204	923-7581

STATUTORY AUTHORITIES

Occupational Safety and Health Act of 1970

Public Law 91-596

For a brief history of this Act, please refer to the introductory section on the Occupational Safety and Health Administration.

Key Sections of Act--Toxics Focus

sec. 20(a)(2)	Authorizes the Secretary of Health, Education, and Welfare (HEW) (as of May 4, 1980--Department of Health and Human Services (DHHS)) to undertake various types of research relating to toxic substances in the work environment in order to meet his responsibility for the formulation of health and safety standards under this Act.
sec. 20(a)(5)	Allows the Secretary of HEW (now DHHS) to develop regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which may endanger the health or safety of employees.
sec. 20(a)(6)	Directs the Secretary of HEW (now DHHS) to provide annually a "list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur."
sec. 20(a)(e)	Delegates the functions of the Secretary of HEW (now DHHS) under this Act of the Director of NIOSH.
sec. 21	Directs the Secretary of HEW (now DHHS) to conduct education and training programs to ensure an adequate supply of personnel to carry out this Act.
sec. 22(c)	Authorizes NIOSH to develop and recommend occupational safety and health standards and to perform all functions of the Secretary of HEW (now DHHS) under section 20 and 21 of this Act.

sec. 22(a)	Establishes NIOSH within HEW (now DHHS) to perform the Secretary of HEW's functions under sections 20 and 21 of this Act.

Federal Mine Safety and Health Amendments Act of 1977

Public Law 95-164

The Federal Mine Safety and Health Amendments Act of 1977 was signed by President Carter on November 9, 1977.

The law is the first to bring all mines in the U. S.--more than 20,000 underground and surface, coal and non-coal facilities--under a single safety and health program. It is also the first safety and health program to cover all of the Nation's 400,000 miners.

The Act repeals the Federal Metal and Nonmetallic Mine Safety Act of 1966 and embodies many aspects of the Coal Mine Health and Safety Act of 1969, strengthening its provisions and expanding its scope to cover all mines.

On March 9, 1978, (120 days after enactment) responsibility for enforcing and administering mine safety and health was transferred from the U. S. Department of the Interior to the U. S. Department of Labor. The act created a new Mine Safety and Health Administration headed by an assistant secretary of labor.

The law also established an independent, five-member Federal Mine Safety and Health Review Commission to decide on appeals of enforcement of actions by mine operators or representatives of miners.

Key Sections of Act--Toxics Focus

sec. 101(a)(6)(b)	Stipulated that for each toxic material or harmful agent found in a mine, NIOSH must determine potential toxicity at concentrations used or found in the mine.
sec. 103(a)	Authorizes NIOSH to make inspections in mines to obtain information on health and safety conditions and mandatory standards.
sec. 501(a)	Authorizes NIOSH to engage in research activities relating to mine safety and health.

Toxic Substances Control Act

Public Law 94-469

The Toxic Substances Control Act was signed on October 11, 1976. This law establishes a committee to recommend for priority rulemaking a list of chemical substances and mixtures known to cause or contribute to cancer, gene mutations, or birth defects.

Key Sections of Act--Toxics Focus

sec. 4	Provides for consultation on toxicological tests and epidemiology and service on the Toxic Substances Selection Committee.

Comprehensive Environmental Response, Compensation, and Liability Act of 1980

Public Law 96-510

This law, enacted December 11, 1980, creates within the Public Health Service an agency to be known as the Agency for Toxic Substances and Disease Registry. Established within the Centers for Disease Control, this agency is to (1) maintain a national registry of persons exposed to toxic substances; (2) maintain a listing of areas closed or restricted in use because of toxic substances contamination; (3) provide appropriate medical care and testing to exposed individuals in case of public health emergencies related to exposure to toxic substances; and (4) to conduct periodic survey and screening programs to determine relationships between exposure to toxic substances and illness.

Key Sections of Act--Toxics Focus

sec. 104	Stipulates cooperation in implementing hazardous waste cleanup.
sec. 111	Protects workers at hazardous waste cleanup.

TOXICS-RELATED ACTIVITIES*

Current programs within NIOSH are divided into four major areas: research, criteria documentation and standards development, technical assistance, and manpower development. Summaries of the first three areas are included in this section.

Research

The largest effort within NIOSH, both in terms of dollars and personnel, is directed toward applied occupational safety and health research. Most of the research is concerned with developing new or modifying existing criteria for recommended occupational safety and health standards. Primary areas of research are toxicology, physical and chemical agents, physiology and ergonomics, engineering, behavioral and motivational factors, and epidemiological industry-wide studies. Several of these areas are highlighted below.

A major objective of the toxicology research is to determine acute, subchronic, and chronic toxicities of new or existing industrial chemicals in the workplace. These data, besides being used for the development of criteria documents, are also utilized to calculate a relative hazard index for each material tested and to identify the most dangerous routes of exposure.

NIOSH's Industry-wide Studies Program develops basic information to be included in the development of the recommended standards. The objectives of this program are: to determine the health experience of current or former workers; to evaluate the industrial environment in terms of stressful agents present, degree of exposure, sources of contaminants, and present controls; to develop, to the extent possible, an exposure-response relationship between each agent or combination of agents and incidence of specific diseases; to devise medical examination procedures which will detect in employees the effects of exposures to harmful agents; and to formulate sampling methods and environmental survey strategies.

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*Included are those activities identified as toxics-related from the information provided at the time of publication. It is recognized that some activities may have been inadvertently omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Chemical Coordination Staff.

These research efforts are undertaken at the NIOSH research labs (located in Cincinnati, Ohio, and Morgantown, West Virginia) and under contract with universities and private research institutes.

Criteria Documentation and Standards Development

Criteria Documents. NIOSH provides recommended safety and health standards in the form of criteria documents to the Secretary of Labor for promulgation and enforcement. Criteria documents are publications on specific occupational safety and health problems. The development of criteria documents includes not only the recommendation of the environmental limit where information is available to support it, but also the recommendation of work practice controls, medical evaluation, information for the workers to recognize and avoid the hazard, and identification of specific research gaps identified during the development of the criteria document.

Subjects may include individual chemicals or physical agents, classes or groups of chemicals or agents, industries, occupations, or specific processes within an industry. The order of hazards selected for criteria development is determined by a NIOSH priority system based on the number of workers exposed; severity of the toxic response, including carcinogenicity; amount of material being used, produced, or handled; and new information regarding occupational health hazards.

The criteria documents are prepared by the Division of Standards Development and Technology Transfer located in Cincinnati, Ohio.

Special Hazard Reviews. The complex and time-consuming criteria documentation process is not always appropriate for particularly hazardous substances, including some carcinogens. For these hazards, NIOSH developed a Special Hazard Review which contains information on the hazard's known health effects, recommended good work practices and exposure levels, suggested monitoring and recordkeeping requirements, and sampling methods.

Emergency Temporary Standards. Where NIOSH determines that worker health protection requires immediate action, a recommended emergency temporary standard is developed and sent to OSHA. The preparation of an emergency temporary standard may be intitiated as a result of OSHA's compliance experience or because of a report of adverse health reports from industry, research groups, or other interested parties. Information obtained as a result of NIOSH field studies or a health hazard evaluation report can also result in the development of emergency temporary standards.

Technical Services

NIOSH provides a number of technical services to employees, employers, and organizations in the occupational safety and health field. These include:

- Health Hazard Evaluations. A Health Hazard Evaluation is a an on-site investigation of health hazards in a specific workplace. The evaluations may be requested by an authorized representative of employees or by an employer. If a NIOSH investigator finds any employees in imminent danger, the employers and the Department of Labor are notified immediately. In cases where there is no imminent danger, NIOSH will mail a copy of the findings to the employer or employee who requested the evaluation. NIOSH was also given authority to perform evaluation in mines under the Federal Mine Safety and Health Act of 1977.

  Contact: Division of Surveillance, Hazard Evaluations, and Field Studies.

- Current Intelligence Bulletins. The Bulletins serve as a means to promptly notify occupational health professionals of health and safety hazards that previously may not have been recognized. The Bulletin is based on the evaluation of new information on a particular hazard in light of other known epidemiology, production, and use data. Since accuracy and speed are of the utmost importance, the review and evaluation process preceding issuance takes only 3 to 4 weeks.

  Contact: Division of Standards Development and Technology Transfer.

- Registry of Toxic Effects of Chemical Substances. Annual publication of the registry is mandated by the OSH Act. The registry itself is a compendium of unevaluated toxicity data abstracted from scientific literature. The format permits searches by groupings of chemicals or by chemical structure. The current edition (1981-82) lists over 59,000 different substances.

  Contact: Division of Standards Development and Technology Transfer.

- Respirator Program. In cooperation with industry, labor, universities and respirator manufacturers, NIOSH tests and certifies respirators, performs field investigations, and conducts research.

  Contact: Division of Safety Research.

- Trade Name Ingredients File. This data base includes ingredient information from the manufacturers of the nearly 100,000 trade name products. Represented are chemical and physical agents found to be used in a sample of about 4,000 worksites.

  Contact: Division of Surveillance, Hazard Evaluations, and Field Studies.

- Training Program. NIOSH offers a full schedule of short courses in industrial hygiene, occupational safety, industrial toxicology, occupational health nursing, and occupational medicine.

  Contact: Division of Training and Manpower Development.

CENTER FOR ENVIRONMENTAL HEALTH

Department of Health and Human Services
Public Health Service
Centers for Disease Control

HEADQUARTERS

Centers for Disease Control
Atlanta, Georgia 30333

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The Centers for Disease Control (CDC), under the Authority of Section 301 of the Public Health Service Act, carries out the overall mission to lead public health efforts to prevent disease, disability and death and to enhance the health of the American people.

In the first major organizational change since 1973, CDC was reorganized in 1980 to enhance the fulfillment of its mission for the improvement of disease prevention and health promotion activities.

The CDC, as reorganized, will carry out its functions through six operational bureau-level Centers.

The goal of the Center for Environmental Health (CEH), the CDC component responsible for environmental public health, including toxic substances activities, is to prevent or control environmentally-related health problems occurring outside the workplace. To accomplish this, CEH conducts programs designed to assist the public health community in the surveillance, investigation, analysis, prevention and control of environmentally induced health problems such as cancer, birth defects, injuries, environmental hazards and related chronic diseases. As the focus within the Department of Health and Human Services (DHHS) for environmental public health program services and emergency response, the Center has been authorized to act on behalf of the Department for the health activities to be conducted under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Superfund)*. The Center also serves as the coordinating point in the Public Health Service (PHS) for the review of Environmental Impact Statements (in accordance with the National Environmental Policy Act) and for radiation emergency planning to better respond to accidents such as the Three Mile Island nuclear reactor leak.

Located at the Chamblee, Georgia facility of the CDC complex, the Center's 300 person staff provides for the administrative, programmatic and laboratory support of a variety of environmental health programs.

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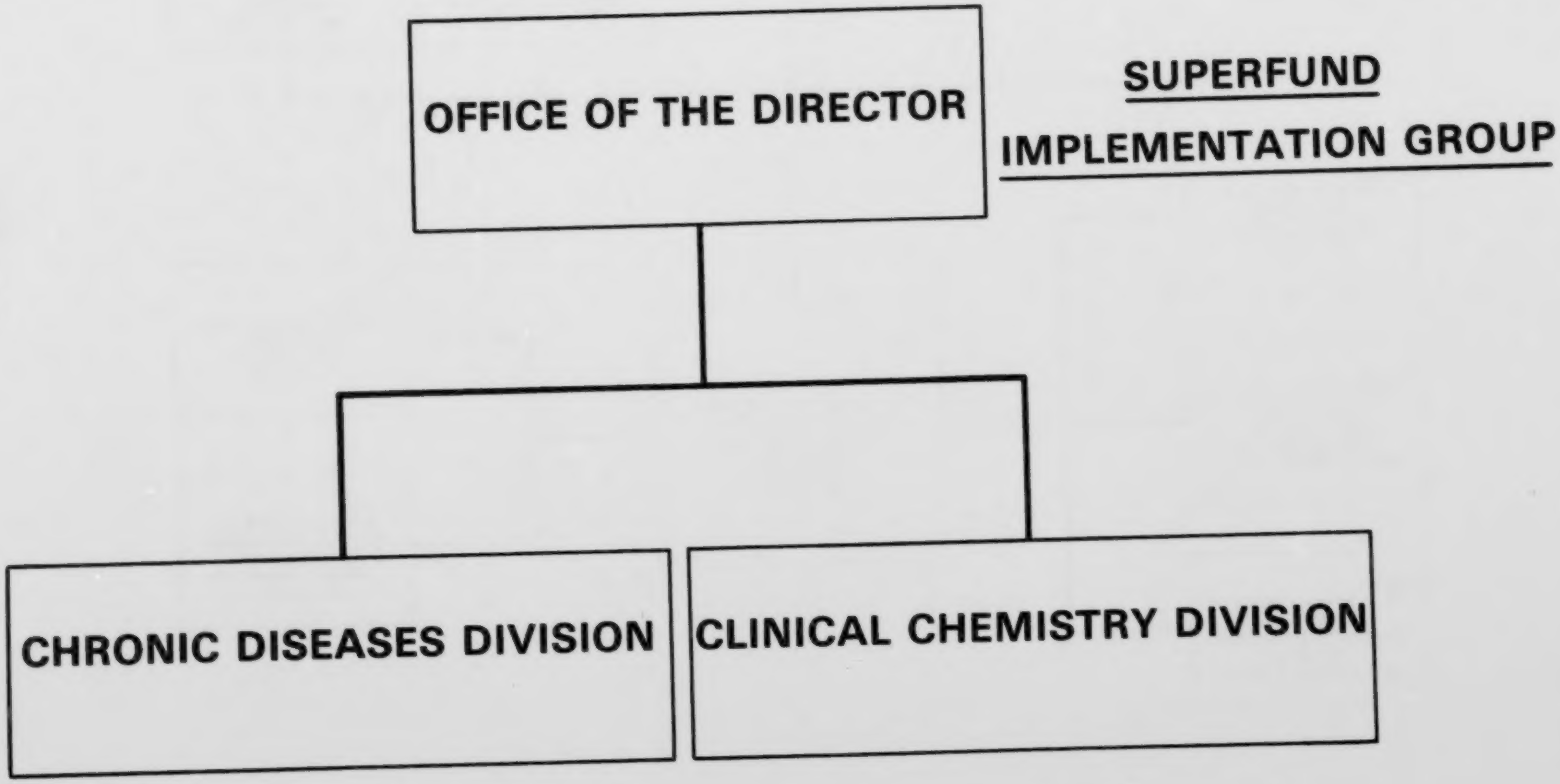
*On April 25, 1983, the Secretary of Health and Human Services established within the Public Health Service a new Agency for Toxic Substances and Disease Registries (ATSDR) which will carry out the health-related authorities and programs of Superfund. The new agency will be located in the CDC facility in Atlanta, Georgia. The Assistant Administrator and other agency staff can be reached at (404) 452-4111 or FTS-236-4111.

The Center also provides technical advice and assistance through a staff of eight Public Health Advisors assigned to the Environmental Protection Agency (EPA) regional offices to assist EPA and the State and local public health officials in their efforts to address toxic chemical spills and waste dump hazards under the Superfund program.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
CENTER FOR ENVIRONMENTAL HEALTH
ORGANIZATIONAL CHART



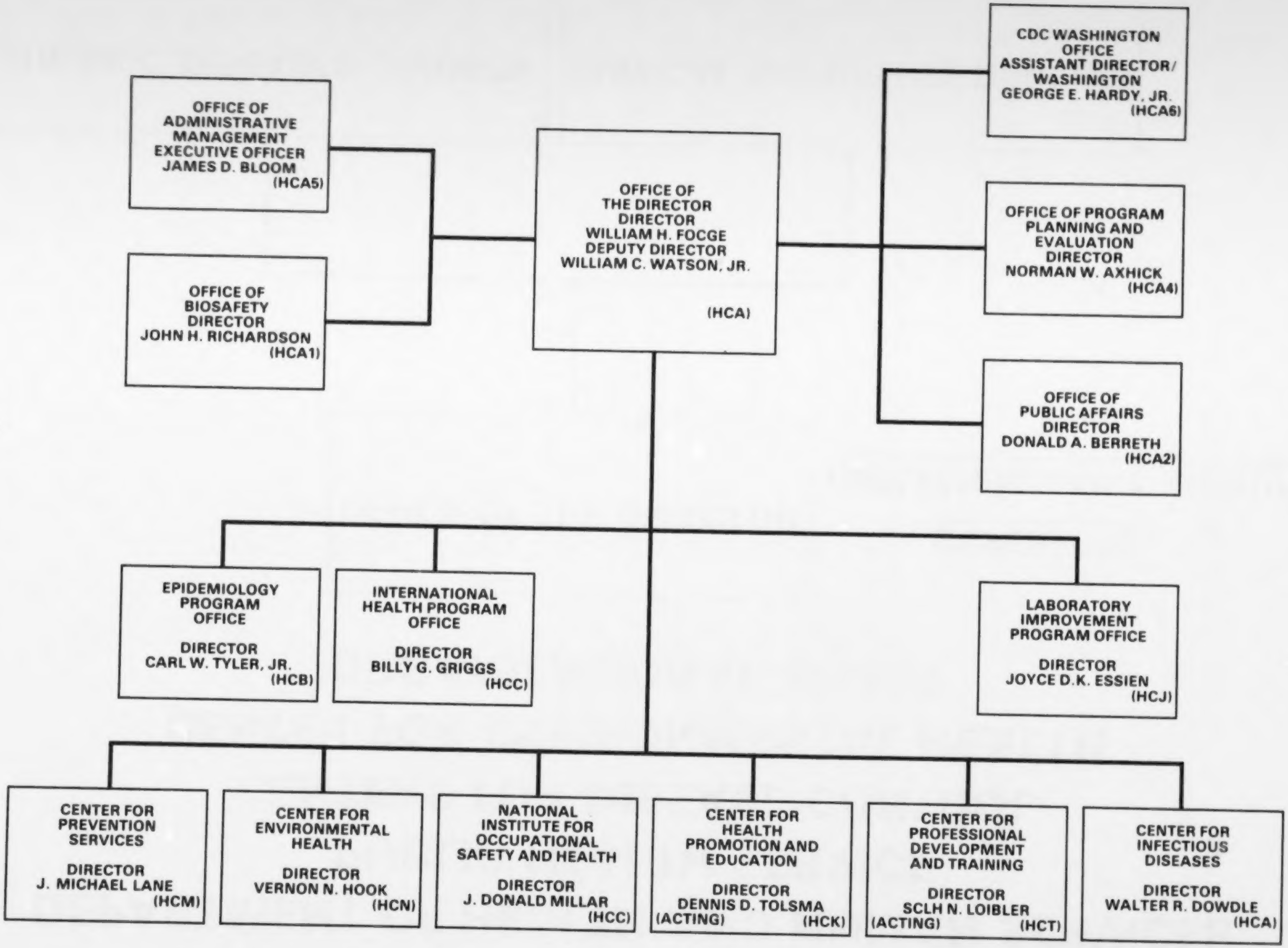
OFFICE OF THE DIRECTOR

SUPERFUND IMPLEMENTATION GROUP

CHRONIC DISEASES DIVISION

CLINICAL CHEMISTRY DIVISION

PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL (HC)


OFFICE OF ADMINISTRATIVE MANAGEMENT EXECUTIVE OFFICER JAMES D. BLOOM (HCA5)
OFFICE OF BIOSAFETY DIRECTOR JOHN H. RICHARDSON (HCA1)
OFFICE OF THE DIRECTOR DIRECTOR WILLIAM H. FOGGE DEPUTY DIRECTOR WILLIAM C. WATSON, JR. (HCA)
CDC WASHINGTON OFFICE ASSISTANT DIRECTOR/ WASHINGTON GEORGE E. HARDY, JR. (HCA6)
OFFICE OF PROGRAM PLANNING AND EVALUATION DIRECTOR NORMAN W. AXHICK (HCA4)
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INTERNATIONAL HEALTH PROGRAM OFFICE DIRECTOR BILLY G. GRIGGS (HCC)
LABORATORY IMPROVEMENT PROGRAM OFFICE DIRECTOR JOYCE D.K. ESSIEN (HCJ)
CENTER FOR PREVENTION SERVICES DIRECTOR J. MICHAEL LANE (HCM)
CENTER FOR ENVIRONMENTAL HEALTH DIRECTOR VERNON N. HOOK (HCN)
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH DIRECTOR J. DONALD MILLAR (HCC)
CENTER FOR HEALTH PROMOTION AND EDUCATION DIRECTOR DENNIS D. TOLSMA (ACTING) (HCK)
CENTER FOR PROFESSIONAL DEVELOPMENT AND TRAINING DIRECTOR SCLH N. LOIBLER (ACTING) (HCT)
CENTER FOR INFECTIOUS DISEASES DIRECTOR WALTER R. DOWDLE (HCA)

DECEMBER 1982

ORGANIZATION*

Office of the Director, Superfund Implementation Group

- Coordinates activities of CEH staff members to provide on-scene medical, technical and epidemiological assistance to Environmental Protection Agency (EPA), other Federal agencies, and State and local health officials in evaluating site contamination and protection of public health and worker safety.
- Maintains and makes available at the field response level, current information on the human health risks of toxic substances.
- As the focal point within DHHS for Superfund activities, provides coordination of the available scientific expertise present in a wide variety of PHS programs including: CDC's National Institute for Occupational Safety and Health, the National Institute of Health's (NIH) National Library of Medicine, the DHHS's National Toxicology Program, and the Food and Drug Administration.

Chronic Disease Division

- Conducts epidemiological investigations of risk factors to human health environmental contamination problems.
- Provides technical input into Superfund site assessment activities.
- Provides consultation to Federal, State and local health officials on a variety of environmental health problems.
- Carries out genetic research to determine the effect of toxic chemical exposure on genetic diseases trends.

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*NOTE: Only those offices which deal with toxic effects or toxic-related issues are developed in this section.

Clinical Chemistry Division

- Provides laboratory support to toxic substances activities within the Center.
- Provides assistance to State public health laboratories through the development of analytical methods and materials for toxicological research.
- Provides support to proficiency testing programs relating to toxic substances testing.

STATUTORY AUTHORITIES

Public Health Service Act

Section 301 Provides assistance to conduct and promote research, investigations, experiments, demonstrations and studies relating to the causes, diagnosis, treatment and control and prevention of physical and mental diseases and impairments in man.

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund)

Executive Order 12316 - delegates authorities for these sections to the Secretary of HHS.

Sections:

- o 104(b) authorizes the President to undertake investigations, monitoring surveys, testing and other information gathering to determine the extent of danger to the public health or welfare....
- o 104 (i) establish an agency, to be known as the Agency for Toxic Substances and Disease Registry. The Administrator of such Agency shall:

(1) "...establish and maintain a national registry of serious diseases and illnesses and a national registry of persons exposed to toxic substances."

(2) "establish and maintain inventory of literature, research, and studies on the health effects of toxic substances."

(3) "...establish and maintain a complete listing of areas closed to the public or otherwise restricted in use because of toxic substance contamination."

(4) "in case of public health emergencies caused or believed to be caused by exposure to toxic substances, provide medical care and testing of exposed individuals...."

(5) "...conduct periodic survey and screening programs to determine relationships between exposure to toxic substances and illness. In cases of public health

emergencies, exposed persons shall be eligible for admission to hospitals and other facilities and services operated by the Public Health Service."

- 301 (f) "...shall study and, not later than two years after the enactment of this Act, shall modify the National Contingency Plan to provide for the protection of the health and safety of employees involved in response actions."

TOXICS-RELATED ACTIVITIES

Birth Defects Monitoring Program. This program was implemented in 1974. It maintains current, national surveillance of birth defects among about 25 percent of U. S. births. Some 150 separate birth defect categories are monitored for incidence trends. This program will allow the Center to determine the effect of environmental agents on birth defects occurrence and will indicate progress or lack of progress in reducing birth defect occurrence.

Veterans Birth Defects Study (Agent Orange). Agent Orange, a defolient used in Vietnam, has been suspected of causing birth defects in children of U. S. Armed Forces exposed to Agent Orange. This study, a major epidemiologic analytical study, will assess the possible relationship of birth defects in the offspring of veterans of service in Vietnam. The study will draw on the Metropolitan Atlanta Congenital Defects Program (MACDP) and a data base source for defect cases. The MACDP maintains a registry of all babies born with birth defects detected near birth in the five-county metropolitan Atlanta area and provides an excellent base for studies of this type.

Genetics. The health effects of environmental exposure are influenced by the unique genetic makeup of each individual. Environmental factors can induce genetic damages in both somatic and germ cells. The genetic changes in somatic cells may lead to cancer, and gene damage in germ cells can result in pollution of the human gene pool causing increases of genetic diseases in future generations. The Genetics Laboratory of the Center is concerned with the quantification of cellular and genetic damage (chromosome breakage, sister chromatid exchange, chromosomal fragile sites, cell metabolic assays) resulting from exposure to environmental agents. Research methods are being applied to a study of human cells in order to refine, improve and establish assay systems which will allow detection of human susceptibility to environmental toxins.

Detection and Measurement of Toxic or Hazardous Substances. As more toxic chemicals are used by industry and agriculture, the threat of human exposure becomes greater. The Center is concerned with this threat and through the Clinical Chemistry and Toxicology Laboratories is attempting to address the problem. Low level exposure to chemical agents and the resultant impact upon human health must be assessed in order to provide appropriate protection to the community. The mass spectrometer, recently installed and calibrated at CDC, allows the Clinical Chemistry Division to detect and measure chemical substances such as polybrominated biphenyls (PBBs), polychlorinated biphenyls (PCB's), dioxins, metals and other elements at trace levels in biologic samples. Definitive identification and quantification of trace organic compounds such as these is the first step in evaluating the impact of toxic chemical exposure on the human system.

Superfund. Congress, recognizing the need to help States and local communities address the growing problem of dealing with toxic chemical spills and waste dump hazards, established the Comprehensive Environmental Response, Compensation and Liability Act of 1980. The Act established a fund, through a system of tariffs on the manufacture of toxic substances, for addressing these hazardous situations. Under the authority of the Act, DHHS is responsible for the health aspects of the program, the lead for which has been delegated administratively to CDC. Within CDC, CEH, through the Superfund Implementation Group, developed and is implementing a comprehensive program to address the environmental hazards posed by these dumps and toxic chemical spills, utilizing expertise from various PHS agencies. These activities are being carried out in cooperation with EPA and other Federal, State and local agencies.

DEPARTMENT OF LABOR

200 Constitution Avenue NW.
Washington, D.C. 20210

Locator: 202-523-6666
Information: 202-523-7304

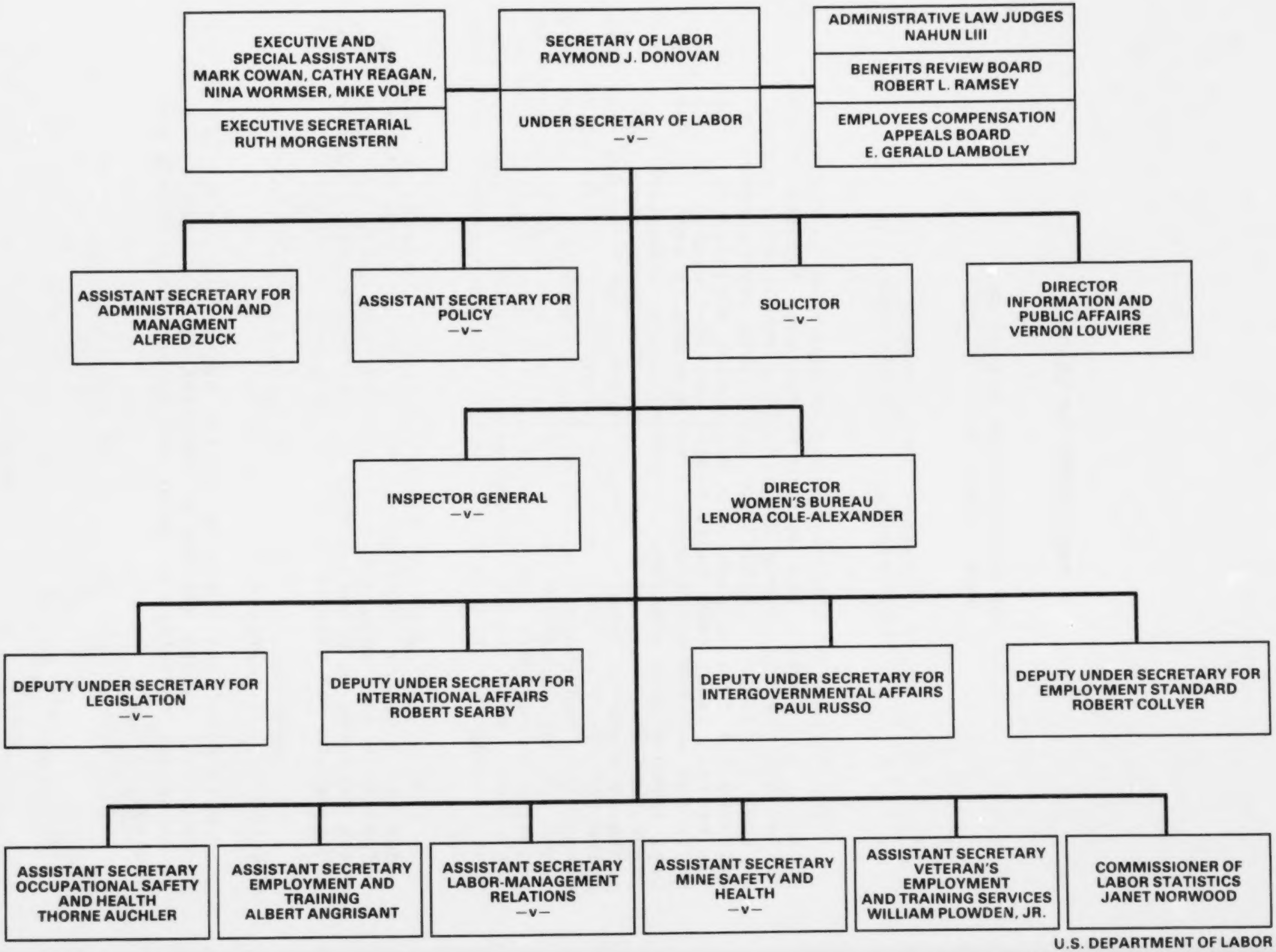
The purpose of the Department of Labor is to foster, promote, and develop the welfare of the wage earners of the United States, to improve their working conditions, and to advance their opportunities for profitable employment. In carrying out this mission, the Department administers: more than 130 Federal labor laws guaranteeing workers' rights to safe and healthful working conditions; a minimum hourly wage and overtime pay; freedom from employment discrimination; unemployment insurance; and workers' compensation. The Department also protects workers' pension rights; sponsors job training programs; helps workers find jobs; works to strengthen free collective bargaining; and keeps track of changes in employment, prices, and other national economic measurements. As the Department seeks to assist all Americans who need and want to work, special efforts are made to meet the unique job market problems of older workers, youths, minority group members, women, the handicapped, and other groups.

A Bureau of Labor was first created by Congress in 1884 under the Interior Department. The Bureau of Labor later become independent as a Department of Labor without executive rank. It again returned to bureau status in the Department of Commerce and Labor, which was created by act of February 14, 1903.

The Department of Labor, ninth executive department, was created by act approved March 4, 1913.

This publication focuses on the duties and activities of the Occupational Safety and Health Administration, which is headed by an Assistant Secretary of Labor for Occupational Safety and Health.

U.S. DEPARTMENT OF LABOR



EXECUTIVE AND
SPECIAL ASSISTANTS
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NINA WORMSER, MIKE VOLPE

EXECUTIVE SECRETARIAL
RUTH MORGENSTERN

SECRETARY OF LABOR
RAYMOND J. DONOVAN

UNDER SECRETARY OF LABOR
—V—

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NAHUN LIII

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ROBERT L. RAMSEY

EMPLOYEES COMPENSATION
APPEALS BOARD
E. GERALD LAMBOLEY

ASSISTANT SECRETARY FOR
ADMINISTRATION AND
MANAGMENT
ALFRED ZUCK

ASSISTANT SECRETARY FOR
POLICY
—V—

SOLICITOR
—V—

DIRECTOR
INFORMATION AND
PUBLIC AFFAIRS
VERNON LOUVIERE

INSPECTOR GENERAL
—V—

DIRECTOR
WOMEN'S BUREAU
LENORA COLE-ALEXANDER

DEPUTY UNDER SECRETARY FOR
LEGISLATION
—V—

DEPUTY UNDER SECRETARY FOR
INTERNATIONAL AFFAIRS
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DEPUTY UNDER SECRETARY FOR
INTERGOVERNMENTAL AFFAIRS
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DEPUTY UNDER SECRETARY FOR
EMPLOYMENT STANDARD
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ASSISTANT SECRETARY
OCCUPATIONAL SAFETY
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TRAINING
ALBERT ANGRISANT

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RELATIONS
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ASSISTANT SECRETARY
MINE SAFETY AND
HEALTH
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ASSISTANT SECRETARY
VETERAN'S
EMPLOYMENT
AND TRAINING SERVICES
WILLIAM PLOWDEN, JR.

COMMISSIONER OF
LABOR STATISTICS
JANET NORWOOD

U.S. DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

Department of Labor
200 Constitution Avenue NW.
Washington, D.C. 20210

Locator: 202-523-6666
Information: 202-523-8151

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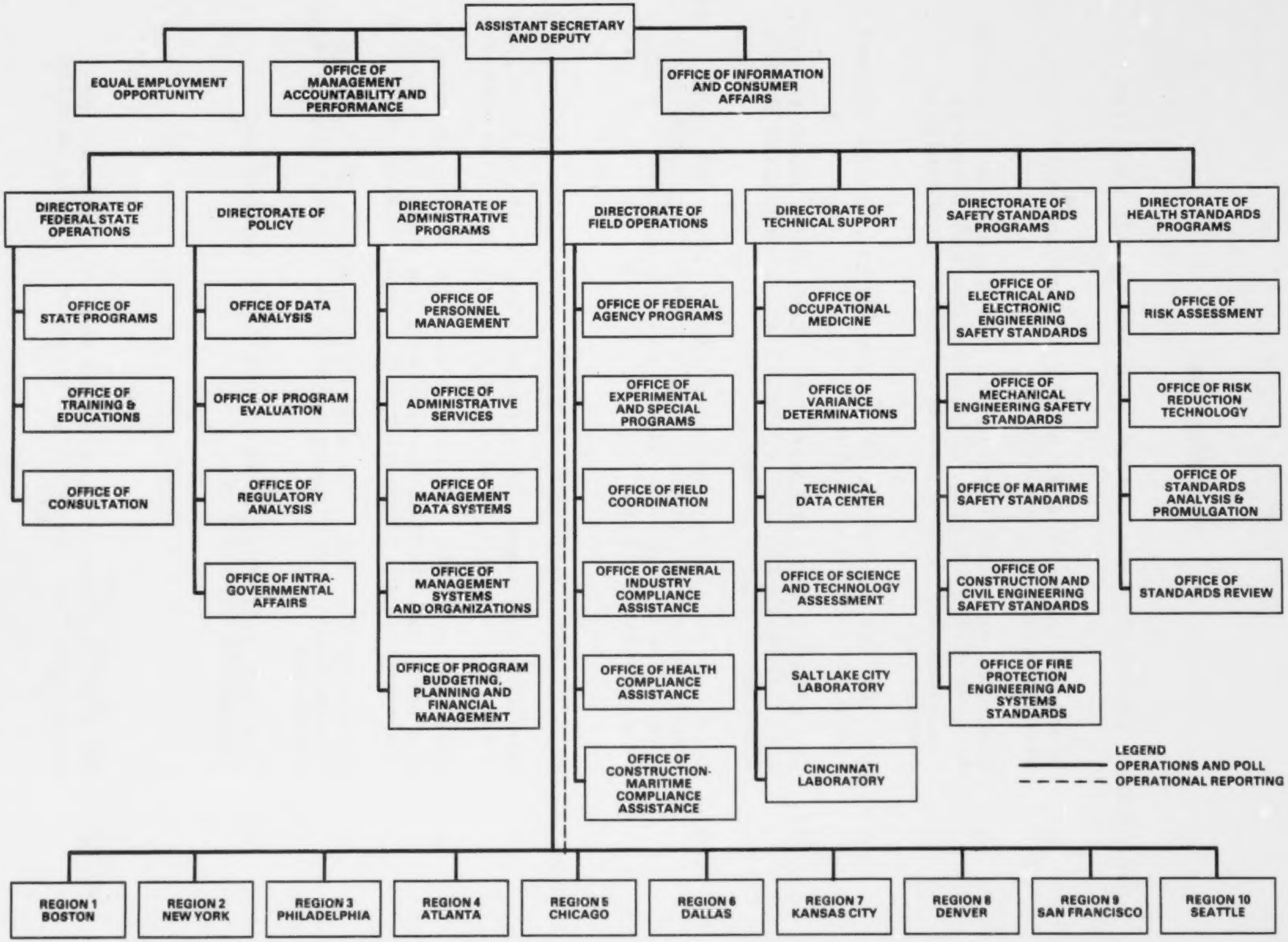
The Occupational Safety and Health Administration (OSHA) is the Agency within the U.S. Department of Labor responsible for administering and enforcing the Occupational Safety and Health Act of 1970. Under the provisions of the Act, OSHA is to develop and enforce mandatory job safety and health standards to "...assure as far as possible [that] every working man and woman in the Nation [has] safe and healthful working conditions..." and to:

- o Encourage employers and employees to reduce hazards in the workplace and to implement new or improve existing safety and health programs.
- o Establish "separate but dependent responsibilities and rights" for employers and employees for the achievement of better safety and health conditions.
- o Establish reporting and recordkeeping procedures to monitor job-related injuries and illnesses.
- o Encourage the development of "fully effective" job safety and health programs by the States. These programs' standards must be at least as effective as

those of the Federal program. (As of June 1983, 24 states or jurisdictions had established their own OSH programs.)

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION


ASSISTANT SECRETARY AND DEPUTY
EQUAL EMPLOYMENT OPPORTUNITY
OFFICE OF MANAGEMENT ACCOUNTABILITY AND PERFORMANCE
OFFICE OF INFORMATION AND CONSUMER AFFAIRS
DIRECTORATE OF FEDERAL STATE OPERATIONS
OFFICE OF STATE PROGRAMS
OFFICE OF TRAINING & EDUCATIONS
OFFICE OF CONSULTATION
DIRECTORATE OF POLICY
OFFICE OF DATA ANALYSIS
OFFICE OF PROGRAM EVALUATION
OFFICE OF REGULATORY ANALYSIS
OFFICE OF INTRA-GOVERNMENTAL AFFAIRS
DIRECTORATE OF ADMINISTRATIVE PROGRAMS
OFFICE OF PERSONNEL MANAGEMENT
OFFICE OF ADMINISTRATIVE SERVICES
OFFICE OF MANAGEMENT DATA SYSTEMS
OFFICE OF MANAGEMENT SYSTEMS AND ORGANIZATIONS
OFFICE OF PROGRAM BUDGETING, PLANNING AND FINANCIAL MANAGEMENT
DIRECTORATE OF FIELD OPERATIONS
OFFICE OF FEDERAL AGENCY PROGRAMS
OFFICE OF EXPERIMENTAL AND SPECIAL PROGRAMS
OFFICE OF FIELD COORDINATION
OFFICE OF GENERAL INDUSTRY COMPLIANCE ASSISTANCE
OFFICE OF HEALTH COMPLIANCE ASSISTANCE
OFFICE OF CONSTRUCTION-MARITIME COMPLIANCE ASSISTANCE
DIRECTORATE OF TECHNICAL SUPPORT
OFFICE OF OCCUPATIONAL MEDICINE
OFFICE OF VARIANCE DETERMINATIONS
TECHNICAL DATA CENTER
OFFICE OF SCIENCE AND TECHNOLOGY ASSESSMENT
SALT LAKE CITY LABORATORY
CINCINNATI LABORATORY
DIRECTORATE OF SAFETY STANDARDS PROGRAMS
OFFICE OF ELECTRICAL AND ELECTRONIC ENGINEERING SAFETY STANDARDS
OFFICE OF MECHANICAL ENGINEERING SAFETY STANDARDS
OFFICE OF MARITIME SAFETY STANDARDS
OFFICE OF CONSTRUCTION AND CIVIL ENGINEERING SAFETY STANDARDS
OFFICE OF FIRE PROTECTION ENGINEERING AND SYSTEMS STANDARDS
DIRECTORATE OF HEALTH STANDARDS PROGRAMS
OFFICE OF RISK ASSESSMENT
OFFICE OF RISK REDUCTION TECHNOLOGY
OFFICE OF STANDARDS ANALYSIS & PROMULGATION
OFFICE OF STANDARDS REVIEW
LEGEND
OPERATIONS AND POLL
OPERATIONAL REPORTING
REGION 1 BOSTON
REGION 2 NEW YORK
REGION 3 PHILADELPHIA
REGION 4 ATLANTA
REGION 5 CHICAGO
REGION 6 DALLAS
REGION 7 KANSAS CITY
REGION 8 DENVER
REGION 9 SAN FRANCISCO
REGION 10 SEATTLE

ORGANIZATION*

DIRECTORATE OF POLICY LEGISLATION, AND REGULATORY ANALYSIS

- Develops and evaluates agency policy in coordination with other OSHA Directorates.
- Analyzes proposed legislation and Executive Orders to determine effect upon OSHA programs and prepares testimony for OSHA witnesses before congressional committees.
- Advises the assistant Secretary as to program options and alternatives available.
- Coordinates OSHA policies and plans with other Federal agencies with related programs and coordinates OSHA's international programs.
- Develops regulatory and economic analyses to support the standard-setting process and assures compliance with applicable executive orders, court decisions and other requirements of law.

DIRECTORATE OF HEALTH STANDARDS PROGRAMS

- Provides workplace standards and regulations to assure healthful working conditions for the Nation's workers.
- Coordinates, with the Directorate of Technical Support, the need for studies to evaluate the various consequences of proposed occupational health standards.
- Maintains liaison with appropriate agencies regarding research and experiments related to occupational health standards.
- Provides information about health standards and rulemaking activities.

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*Note: Only those directorates which deal with toxics or toxics-related issues are discussed in this section.

DIRECTORATE OF TECHNICAL SUPPORT

- Serves as a source of Agency expertise on scientific, environmental, and engineering issues involved in the overall occupational safety and health field.
- Provides medical and epidemiological expertise and support for other OSHA offices.
- Processes variances from the OSHA standards.
- Provides chemical analyses and instrument calibrations to the OSHA compliance officers.
- Operates a clearinghouse of occupational safety and health data (the Technical Data Center).
- Provides rapid response to occupational health related emergencies at the workplace (Health Response Team).
- Maintains public records containing information pertinent to OSHA rulemaking actions (Docket Office).
- Provides chemical analyses and instrument calibration to the OSHA compliance officers.
- Operates a clearinghouse of occupational safety and health data (the Technical Data center).
- Provides rapid response to occupational health related emergencies at the workplace (Health Response Team).
- Maintains public record containing information pertinent to OSHA rulemaking actions (Docket Office).

DIRECTORATE OF FEDERAL COMPLIANCE AND STATE PROGRAMS

- Provides directives on all standards, explaining compliance with standards.

DIRECTORATE OF FIELD COORDINATION

- Responsible for toxics and toxics-related issues when questions of enforcement arise.
- Disseminates information about toxic substances to OSHA field offices.

FOR FURTHER INFORMATION:

Federal and State Agencies:
Chief, Division of Interagency Programs
U. S. Department of Labor--OSHA
200 Constitution Avenue NW.
Room N3628
Washington, D.C. 20210
Phone: 202-523-9296, FTS: 523-9296

Industry and General Public:
Chief, Division of News Media Service
U.S. Department of Labor--OSHA
200 Constitution Avenue NW.
Room N3637
Washington, D.C. 20210
Phone: 202-523-8151
FTS: 523-8151

STATUTORY AUTHORITIES

The Occupational Safety and Health Act of 1970

Public Law 91-596 29 U.S.C. § 651 et seq.

The Occupational Safety and Health Act of 1970 was the result of a concerted effort by Congress to pass nationwide job safety legislation. Prior to 1970, Federal authority for occupational safety and health was confined to a few acts of limited scope (such as the Walsh-Healy Public Contracts Act, which covered workers employed on certain Federal contracts, the McNamara O'Hara Services Contract Act, the Maritime Safety Act, and the Construction Safety Act). Although a number of States had modern laws or sufficient resources to administer and enforce safety and health regulations, some had no plans at all. Before OSHA, the quality and scope of the regulations as well as the effort directed toward enforcement and compliance varied widely, and many States feared that strict adherence to standards would give them a competitive and economic disadvantage.

The Occupational Safety and Health Act is the first comprehensive Federal legislation in the field of occupational safety and health. In general, the Act covers all employers and their employees in the 50 States, the District of Columbia, Puerto Rico, the Canal Zone, and all other territories under Federal Government jurisdiction.

As defined by the Act, an employer is any "person engaged in a business affecting commerce who has employees, but does not include the United States or any State or political subdivision of a State."

Section 19 of the Act specifically delegates responsibility for Federal employee occupational safety and health to the head of each Federal agency. This responsibility is comparable to that of employers in the private sector. If an agency is found to be neglecting any area of occupational safety and health for its workers, OSHA may provide advice and assistance in resolving problems through its Office of Federal Agency Programs.

At this time, 24 States or jurisdictions operate occupational safety and health plans that cover both State and local government employees. State and local government employees of States without such plans are excluded from the coverage of the Act.

Three new agencies were established by the Act to carry out the functions of the statute:

- The Occupational Safety and Health Administration within the Department of Labor, which is responsible for carrying out most of the Secretary's responsibilities under the Act.
- The National Institute for Occupational Safety and Health (NIOSH) within the Department of Health and Human Services (HHS), which is responsible for conducting research in occupational safety and health areas for use by OSHA in the development of health and safety standards.
- An independent Occupational Safety and Health Review Commission to adjudicate enforcement cases, review citations and proposed penalties, establish abatement dates, etc.

In addition to these agencies, the Act established a 12-member National Advisory Committee on Occupational Safety and Health (NACOSH) which meets at least twice a year to advise, consult with, and make recommendations to the Secretary on matters relating to the administration of the Act.

SCOPE OF OSHA ACTIVITIES IN TOXIC SUBSTANCES AREAS

At this time, there are numerous ways in which OSHA activities affect the issue of toxic substances in the workplace. These include:

Existing standards: As of June 1983, OSHA had established standards for many toxic substances found in the workplace. The object of these standards is to eliminate or reduce worker exposure to toxic substances, and thereby reduce the risks of chronic or acute injury in the exposed worker population. OSHA toxics related standards can be found at 29 CFR 1910.1000, et seq. The standards found at 1910.1000 list approximately 400 chemicals and classes of substances for which a permissible exposure limit (PEL) has been established. Standards that follow 1910.1000 are individualized standards for specific chemicals, including some for carcinogens. For example, 1910.1007 is the OSHA standard for 3,3'-Dichlorobenzidine and its salts. Standards such as the one at 1910.1007 include exposure limits, but also have requirements for engineering controls, maintenance and decontamination activities, informational signs, worker training, recordkeeping, etc.

New standards activity: As information is received about workplace hazards, OSHA develops new standards to deal with them. At this time, OSHA is developing standards for a number of toxic substances, including revisions to its standards for asbestos, lead, ethylene oxide, and ethylene dibromide, and is considering revisions to its generic carcinogen policy. See the section titled "Toxic-Related Activities" for a more complete listing of ongoing activities.

Other Standards: OSHA has a number of standards that deal indirectly with toxic substances. For example, some OSHA safety standards deal with the proper care, handling and storage of toxics. General "housekeeping" regulations affect the way toxics are used in industry. OSHA also has a general duty clause (section 5(a)(1) of the OSHA Act), that requires employers to provide a safe and healthful workplace for all employees. The general duty clause may, in specific instances, be used to cover hazardous substance situations that are not already spelled out in OSHA standards. In addition, the proposed Hazard Communication standard and the Access to Employee Medical and Exposure Records rule require the employer to provide information about toxic substances in the workplace.

Enforcement: OSHA has a staff of approximately 1200 compliance officers (and the State OSHA plans have another 1200) which inspects workplaces on a regular basis. This includes inspection for compliance with OSHA health standards, and may require sampling for exposure to hazardous substances. Employers at workplaces found to be out of compliance with OSHA standards may be cited and/or fined, and are required to bring air contaminant exposures at the worksite into line with OSHA standards.

Key Sections of OSHA Act--Toxics Focus

sec. 3	Defines terms of importance.
sec. 5	States the duties of each employer and employee.
sec. 5(a)(1)	Requires the employer to maintain a workplace that is "free from recognized hazards that are causing or are likely to cause death or serious physical

harm to (the) employees." This section may be used to cite hazards for which there is no current OSHA standard. A hazard is "recognized" if the employer's industry recognizes the condition to be a hazard (shown, for example, by trade magazine articles about the hazard) or if the employer has actual knowledge of the hazard (for example, if the employer has bought respirators specifically designed to mitigate against exposure to one substance). The actual presence of the hazard in the workplace must also have been reasonably foreseeable. Thus, for example, excess concentrations of a toxic substance in the air would be a recognized hazard if the presence of the substance is known or should have been known to the employer (or is commonly known to the industry as a whole) and if the actual concentration could have been detected through the use of sampling devices.

sec. 6(b) (1-4)	Authorizes the Secretary to promulgate occupational safety or health standards with provisions for public participation in the rulemaking process.
sec. 6(b)(5)	Details the development of standards for toxic materials or harmful physical agents.
sec. 6(b)(7)	Requires that standards prescribe the use of appropriate forms of warning, suitable protective or control equipment, the monitoring of employee exposure, and medical examinations or tests as may be necessary.
sec. 6(c)(1)	Directs the Secretary to provide for an immediate, emergency temporary standard covering employees exposed to grave danger from exposure to toxic substances, physically harmful agents, or new hazards.
sec. 8	Gives OSHA compliance officers (inspectors) the authority to enter any work area for inspection and investigation (subject to interpretation of *Marshall vs. Barlows, Inc.,* Supreme Court decision).
sec. 9	Authorizes the issuance of a citation to employers who have violated any rule or standard.
sec. 12	Establishes the Occupational Safety and Health Review Commission which affirms, codifies, or vacates citations or proposed penalties.

sec. 13	Authorizes the Secretary to petition the courts to restrain imminent danger situations.
sec. 16	Allows the issuance of variances, tolerances, and exemptions to the Act.
sec. 17	Sets the conditions for penalties.
sec. 20 (a)(2)	Directs the Secretary of Health and Human Services (HHS) to develop specific plans for research, demonstrations, and experiments to produce criteria identifying toxic substances.
sec. 20 (a)(3)	Directs the Secretary of HHS to develop criteria that describe safe exposure levels for toxic materials and hazardous physical agents.
sec. 20 (a)(5)	Allows the Secretary of HHS to develop regulations requiring employers to measure, record, and make reports on employee exposure to substances or physical agents which may endanger employee health or safety.
sec. 20 (a)(6)	Directs the Secretary of HHS to provide annually a "list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur (Registry of Toxic Effects of Chemical Substances (RTECS)).
sec. 22	Establishes the National Institute for Occupational Safety and Health to do research and establish recommended standards.

Regulatory Options Available Under Statute

- o Promulgate occupational safety and health standards, including emergency temporary standards
- o Inspect and investigate hazardous conditions
- o Issue citations and proposed penalties
- o Petition the courts to restrain imminent danger situations

- Approve or reject State plans for administering and enforcing health/safety programs under the Act

REGULATORY DEVELOPMENT

The development of OSHA health standards is a complex process. It requires internal consideration by the agency, coordination with affected parties, as well as review by the Department of Labor and the Office of Management and Budget. While the process itself is complicated, the general policy for standards development is clearly explained by OSHA's directive on the Regulation Management System (OSHA Instruction RUL. 1 CH-1, November 1, 1982). The policy statement for general standards development activities is quoted below:

> The following policies govern standards activities. They are based on the Occupational Safety and Health Act, as interpreted by the courts, and on good administrative practice. They must be adhered to explicitly, except in those extraordinary circumstances when the Assistant Secretary personally approves an exception.
>
> A. Each standard must address a demonstrable significant risk of material health impairment or injury;
>
> B. Alternative approaches, including non-regulatory means, must be explored to mitigate the adverse effects of the risk;
>
> C. Each standard must be reasonably necessary and appropriate to substantially reduce employee risk;
>
> D. Each standard must be shown to be both technically and economically feasible on an industry-by-industry basis to the extent practicable;
>
> E. The cost-effectiveness of alternative approaches must be considered;
>
> F. The most cost-effective approaches which ensure protection from the risk must be chosen;
>
> G. Facts to support the standard must be developed, with special attention given to the documentation of the risk and the technological and economic feasibility of the standard;

H. The public must have an early and meaningful opportunity to participate in the development of each standard. Affected parties, including States, must be requested to provide relevant information concerning risk, feasibility and cost-effectiveness, and all information obtained must be considered fully when developing each standard.

TOXICS-RELATED ACTIVITIES

The following list is adapted from the Unified Agenda published in the Federal Register on April 25, 1983 (48 FR 18184, et seq.). Since rulemaking procedures are sometimes slow and difficult and because timetables are constantly changing, information about proposed completion dates has not been included.

ACCESS TO EMPLOYEE EXPOSURE AND MEDICAL RECORDS

The regulation, promulgated in May 1980 [45 FR 35212], requires employers to preserve and maintain exposure and medical records pertinent to an employee's occupational exposure to toxic substances, and to assure access to these records by employees, designated employee representatives, and OSHA. OSHA has reviewed the regulation and on July 13, 1982 [47 FR 30420] proposed certain modifications, including revisions of the definitions of "toxic substance" and "exposure records," changes in the scope and application of the regulation and additional trade secret protection provisions.

ASBESTOS

OSHA is revising this rule because NIOSH and other sources have provided data to OSHA indicating that the present OSHA permissible exposure limit (PEL) may not adequately protect workers from asbestos-related diseases. The revision will include a change in the PEL and modification of other requirements to assure that industry compliance is achieved in the most cost-effective way.

CARCINOGEN POLICY

The Carcinogen Policy describes the criteria and procedures OSHA will use to identify, classify, and then regulate carcinogens. The Policy also establishes a process for screening chemicals and for setting priorities for potential rulemaking activities. The validity of the scientific criteria set forth in the Policy and the cost effectiveness of the rule are being reexamined. The original standard was issued in 1980 before the Supreme Court "benzene" decision on significant risk. Thereafter, a final rule deleting provisions of the Carcinogen Policy that were inconsistent with the benzene decision was published on 1/19/81 [46 FR 4889]. A proposal was published on 1/23/81 [46 FR 7402] to permit consideration of alternatives to the risk analysis section of the Carcinogen Policy. The proposal was withdrawn on 3/27/81 [46 FR 19000]. A new advance notice of proposed rulemaking was published on 1/5/82 [47 FR 187] with comments due by 4/5/82. That document also proposed to stay the publication of the candidate and priority lists of carcinogenic substances. The end of the comment period on the proposed stay of the candidate and priority lists was 2/19/82. A final decision to stay the lists was published 1/4/83 [48 FR 241].

ETHYLENE DIBROMIDE (EDB)

Since 1970, several independent scientific studies have concluded that ethylene dibromide (EDB) can cause cancer in laboratory animals. In addition, EDB has been shown to be mutagenic in several test systems. This evidence raises serious concern about the adequacy of the current permissible exposure limits for EDB, which were adopted by OSHA in 1971. OSHA published an advance notice of proposed rulemaking for this chemical on December 18, 1981 [46 FR 61671].

ETHYLENE OXIDE (EtO)

OSHA has announced its intention to conduct rulemaking on whether to revise the current standard for ethylene oxide (EtO) because NIOSH and other sources have provided data indicating that the current permissible exposure limit may not be adequate to protect worker health. A proposed rule (NPRM) was published on 4/21/83 [48 FR 1783].

HAZARD COMMUNICATION

The proposed standard would require chemical manufacturers to assess the hazards of chemicals which they produce and to provide information to their employees about these hazards by means of hazards communication programs, including labels, material safety data sheets, and training. The original proposal, published 1/16/81 [46 FR 4412], was withdrawn 2/12/81 [46 FR 12020] to permit further analysis of regulatory alternatives. A new proposal was published 3/19/82 [47 FR 12092]. Public hearings were held in various locations during June and July 1982.

HEALTH HAZARDS OF CHEMICALS IN LABORATORIES

Existing OSHA standards are designed to protect employees who are engaged in work involving exposure to only a few toxic chemicals during relatively standardized, continuous, or repetitive processes. In contrast, laboratory workers are exposed to a multitude of toxic substances under frequently changing or unpredictable conditions. OSHA will examine whether prudent work practices and protective equipment, chosen for the specific facilities and task, are more effective, feasible and economical for laboratory work than adhering to OSHA's current substance-specific exposure standards.

INORGANIC ARSENIC

In 1978, OSHA issued a new regulation reducing the permissible limit for employee exposure to inorganic arsenic. Because of the Supreme Court's decision in *Industrial Union Department v. American Petroleum Institute* (the "benzene" decision 448 U.S. 607 (1980)), the Ninth Circuit Court of Appeals remanded the standard to the Agency to make findings about whether exposure to inorganic arsenic in the workplace posed a significant risk. On 4/9/82 [47 FR 15358], OSHA published a notice reopening the inorganic arsenic rulemaking record for the purpose of receiving evidence and making findings on the degree of risk from occupational exposure to arsenic and the significance of that risk. Public hearings were held 7/13/ - 7/16/82. On 1/14/83 [48 FR 1864], OSHA published a Supplemental Statement of Reasons for the Final Rule and forwarded its findings regarding risk to the Ninth Circuit Court. OSHA is awaiting the Court's decision on this matter.

LEAD

The current standard for occupational exposure to lead was promulgated in 1978. It sets a PEL of 50 micrograms of lead per cubic meter of air [50 ug/m^3], and requires the use of feasible engineering or work practice controls. There are serious questions concerning significant risk, feasibility, and cost effectiveness of the standard in certain industries. Therefore, OSHA has announced its intention to review and reconsider the regulation. The advance notice of proposed rulemaking [46 FR 22764] asked for comments on such issues as economic and technological feasibility and cost effectiveness.

MINE SAFETY AND HEALTH ADMINISTRATION

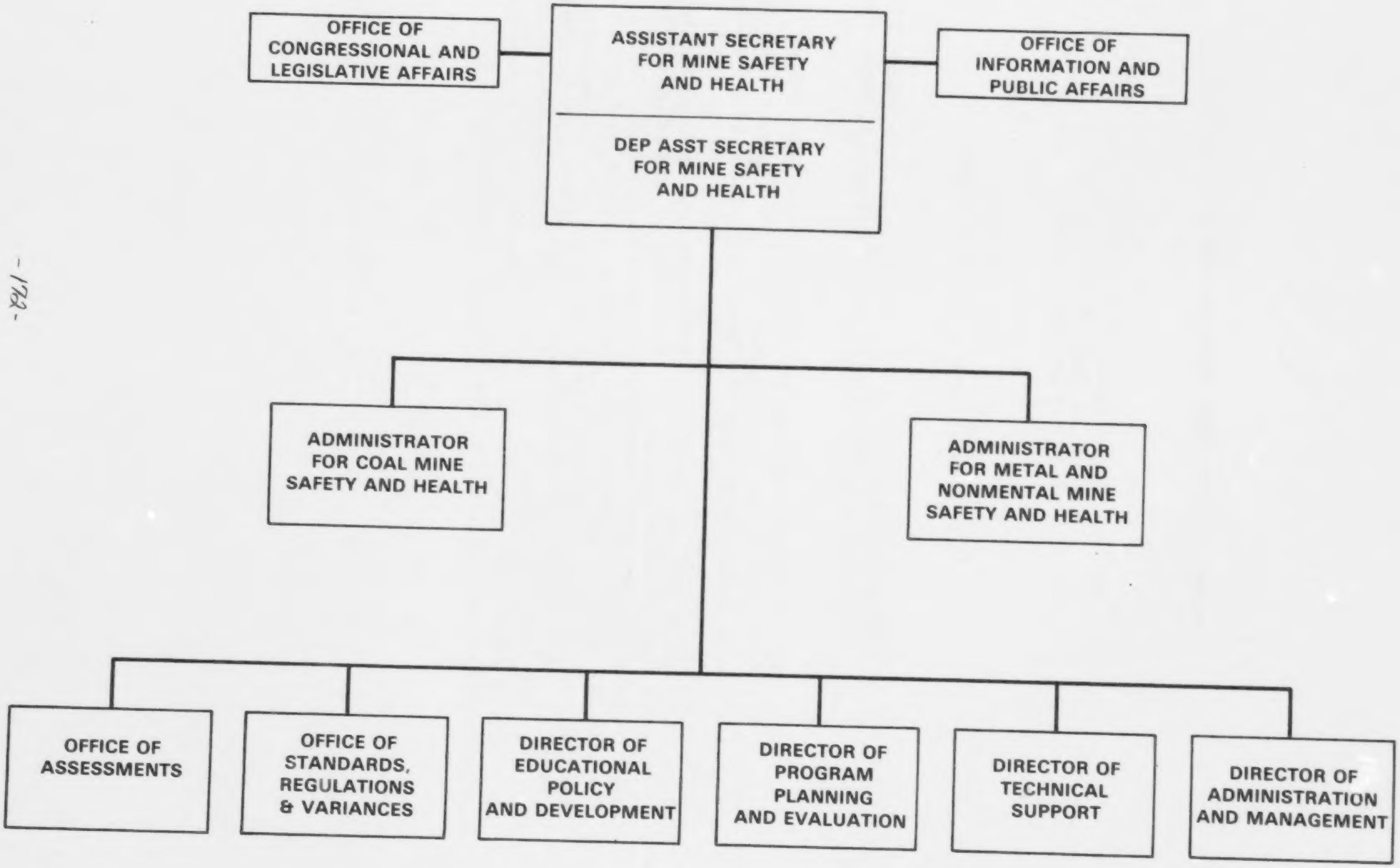
Department of Labor
4015 Wilson Boulevard
Arlington, VA 22203

Locator: 703-235-1470
Information: 703-235-1565

Organization........................Page 173
Statutory Authority.................Page 176

The Mine Safety and Health Administration (MSHA) is the agency within the U. S. Department of Labor responsible for directing and administering the provisions of the Federal Mine Safety and Health Act of 1977 (P.L. 95-164) as a means to eliminate fatalities, reduce the frequency and severity of accidents, and minimize health hazards in the mining industry; to ensure compliance with mandatory Federal safety and health standards; and to promote and improve safety and health conditions in the Nation's mines through effective education and training and technical assistance programs. Among the provisions of the Act, the Secretary of Labor and the Secretary of Health and Human Services are directed to develop and promulgate improved mandatory safety and health standards.

DEPARTMENT OF LABOR
MINE SAFETY AND HEALTH ADMINISTRATION


OFFICE OF CONGRESSIONAL AND LEGISLATIVE AFFAIRS
ASSISTANT SECRETARY FOR MINE SAFETY AND HEALTH
DEP ASST SECRETARY FOR MINE SAFETY AND HEALTH
OFFICE OF INFORMATION AND PUBLIC AFFAIRS
ADMINISTRATOR FOR COAL MINE SAFETY AND HEALTH
ADMINISTRATOR FOR METAL AND NONMENTAL MINE SAFETY AND HEALTH
OFFICE OF ASSESSMENTS
OFFICE OF STANDARDS, REGULATIONS & VARIANCES
DIRECTOR OF EDUCATIONAL POLICY AND DEVELOPMENT
DIRECTOR OF PROGRAM PLANNING AND EVALUATION
DIRECTOR OF TECHNICAL SUPPORT
DIRECTOR OF ADMINISTRATION AND MANAGEMENT

ORGANIZATION*

Coal Mine Safety and Health

- Serves as the principal advisor to and consults with the Assistant Secretary on matters and policies pertaining to the inspection of the Nation's coal mines, mine conditions and practices, and accident and injury prevention.
- Provides direction and leadership in the administration of nationwide coal mine safety and health inspection and assistance programs through a system of District, Subdistrict, and Field Offices located in coal-producing States.
- Formulates and coordinates basic policies, programs, and regulations concerning safety and health in the coal industry.
- Cooperates in the development of coal mine health criteria and standards in furtherance of Department of Health and Human Services responsibilities under the Act.
- Develops new or revised mine safety and health standards for application to coal mines.
- Develops criteria and methods for ensuring compliance with coal mine safety and health standards.
- Provides expertise in analyzing existing and potential safety and health problems in the coal industry.
- Analyzes records and statistics to determine unsafe or unhealthful conditions and events in coal mines demanding immediate attention.

Metal and Nonmetal Mine Safety and Health

- Serves as the principal advisor to and consults with the Assistant Secretary on matters and policies pertaining to the inspection of the Nation's metal and nonmetal mines, mine conditions and practices, and accident and injury prevention.

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* NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Provides direction and leadership in the administration of nationwide metal and nonmetal mine safety and health inspection and assistance programs through a system of District, Subdistrict, and Field Offices located throughout the United States and its territories.
- Formulates and coordinates basic policies, programs, and regulations concerning safety and health in the metal and nonmetal industries.
- Cooperates in the development of metal and nonmetal mine health criteria and standards in furtherance of Department of Health and Human Services responsibilities under the Act.
- Develops new or revised safety and health standards for application to metal and nonmetal mines and mills.
- Develops criteria and methods for ensuring compliance with metal and nonmetal mine safety and health standards.
- Provides expertise in analyzing existing and potential safety and health problems in the metal and nonmetal industries.
- Analyzes records and statistics to determine unsafe or unhealthful conditions and events in metal and nonmetal mines demanding immediate attention.

Technical Support

- Administers nationwide technical assistance program to MSHA officials and the mining industry in furtherance of safety and health in the Nation's mines.
- Formulates and coordinates basic policies, programs, regulations, and standards to ensure the use of safe equipment and materials in mines and the presence of healthful conditions in mines and mills.
- Conducts engineering studies and surveys on problems in the mining industry critical to mine safety and health, and recommends solutions.

- Gathers, analyzes, and publishes accident, injury and occupational illness data to improve MSHA's enforcement programs and to stimulate the continuous improvement of safety and health in the mining industry.

- Conducts indepth studies using mine information to define true cause of accidents, injuries, or occupational illnesses; determines trends and impact; recommends improvements to the mining industry.

- Maintains liaison with the Bureau of Mines (BOM), Department of the Interior, and the National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services, for the purpose of planning, developing, and monitoring mine safety and health research and in disseminating and utilizing research results in MSHA and the mining industry.

Standards, Regulations and Variances

- Advises the Assistant Secretary, appropriate DOL/MSHA officials and others on policy and other matters related to the promulgation of rules, regulations and standards and the granting of variances.

- Promulgates and publishes rules, regulations and standards necessary to implement the Federal Mine Safety and Health Act of 1977.

- Establishes MSHA policies and criteria for drafting of regulations and standards and ensures that regulations/standards are needed.

- Arranges, announces and conducts public hearings and consultation meetings on proposed standards/regulations and evaluates the comments/findings obtained.

- Prepares or coordinates the preparation of environmental and regulatory impact statements.

- Assists in the development of legislative proposals on behalf of the Assistant Secretary.

- Coordinates regulatory/standards matters with other interested Federal, state and local government agencies.

STATUTORY AUTHORITIES

THE FEDERAL MINE SAFETY AND HEALTH ACT OF 1977
PUBLIC LAW 95-164
KEY SECTIONS OF ACT -- TOXICS FOCUS

Section 101(a)(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health and Human Services, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this Act, the Secretary may request the recommendation of an advisory committee appointed under section 102(c). The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health and Human Services, together with all pertinent factual information developed by the Secretary or the Secretary of Health and Human Services or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within 60 days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than 180 days. When the Secretary receives a recommendation, accompanied by appropriate criteria, from the National Institute for Occupational Safety and Health that a rule be promulgated, modified, or revoked, the Secretary must, within 60 days after receipt thereof, refer such recommendation to an advisory committee pursuant to this paragraph, or publish such as a proposed rule pursuant to paragraph (2), or publish in the Federal Register his determination not to do so, and his reasons therefor. The Secretary shall be required to request the recommendations of an advisory committee appointed under section 102(c) if the rule to be promulgated is, in the discretion of the Secretary, which shall be final, new in effect or application and has significant economic impact.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking a mandatory health or safety standard in the Federal Register. If the Secretary determines that a rule should be proposed and in connection therewith has appointed an advisory committee as provided by paragraph (1), the Secretary shall publish a proposed rule, or the reasons for his determination not to publish said rule, within 60 days following the submission of the advisory committee's recommendation or the

expiration of the period of time prescribed by the Secretary in such submission. In either event, the Secretary shall afford interested persons a period of 30 days after any such publication to submit written data or comments on the proposed rule. Such comment period may be extended by the Secretary upon a finding of good cause, which the Secretary shall publish in the Federal Register. Publication shall include the text of such rules proposed in their entirety, a comparative text of the proposed changes in existing rules, and shall include a comprehensive index to the rules, cross-referenced by subject matter.

Section 101(a)(6)(A) The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standards for the period of his working life. Development of mandatory standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(B) The Secretary of Health and Human Services, as soon as possible after the date of enactment of the Federal Mine Safety and Health Amendments Act of 1977 but in no event later than 18 months after such date and on a continuing basis thereafter, shall, for each toxic material or harmful physical agent which is used or found in a mine, determine whether such material or agent is potentially toxic at the concentrations in which it is used or found in a mine. The Secretary of Health and Human Services shall submit such determinations with respect to such toxic substances or harmful physical agents to the Secretary. Thereafter, the Secretary of Health and Human Services shall submit to the Secretary all pertinent criteria regarding any such substances determined to be toxic or any such harmful agents as such criteria are developed. Within 60 days after receiving any criteria in accordance with the preceding sentence relating to a toxic material or harmful physical agent which is not adequately covered by a mandatory health or safety standard promulgated under this section, the Secretary shall either appoint an advisory committee to make recommendations with respect to a mandatory health or safety standard covering such material or agent in accordance with paragraph (1), or publish a proposed rule promulgating such a mandatory health or safety standard in accordance with paragraph (2), or shall publish his determination not to do so.

Section 101(a)(7) Any mandatory health or safety standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to ensure that miners are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such mandatory standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards, and shall provide for monitoring or measuring miner exposure at such locations and intervals, in such manner so as to assure the maximum protection of miners. In addition, where appropriate, any such mandatory standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available, by the operator and at his cost, to miners exposed to such hazards in order to most effectively determine whether the health of such miners is adversely affected by such exposure. Where appropriate, the mandatory standard shall provide that where a determination is made that a miner may suffer material impairment of health or functional capacity by reason of exposure to the hazard covered by such mandatory standard, that miner shall be removed from such exposure and reassigned. Any miner transferred as a result of such exposure shall continue to receive compensation for such work at no less than the regular rate of pay for miners in the classification such miner held immediately prior to his transfer. In the event of the transfer of a miner pursuant to the preceding sentence, increases in wages of the transferred miner shall be based upon the new work classification. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health and Human Services, such examinations may be furnished at the expense of the Secretary of Health and Human Services. The results of examinations or tests made pursuant to the preceding sentence shall be furnished only to the Secretary or the Secretary of Health and Human Services, and, at the request of the miner, to his designated physician.

Section 101(a)(9) No mandatory health or safety standard promulgated under this title shall reduce the protection afforded miners by an existing mandatory health or safety standard.

Section 101(b)(1) The Secretary shall provide, without regard to the requirements of chapter 5, title 5, United States Code, for an emergency temporary mandatory health or safety standard to take immediate effect upon publication of the Federal Register if he determines (A) that miners are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful, or to other hazards, and (B) that such emergency standard is necessary to protect miners from such danger.

(2) A temporary mandatory health or safety standard shall be effective until superseded by a mandatory standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register, the Secretary shall commence a proceeding in accordance with section 101(a), and the standards as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a mandatory health and safety standard under this paragraph no later than nine months after publication of the emergency temporary standards, as provided in paragraph (2).

DEPARTMENT OF TRANSPORTATION

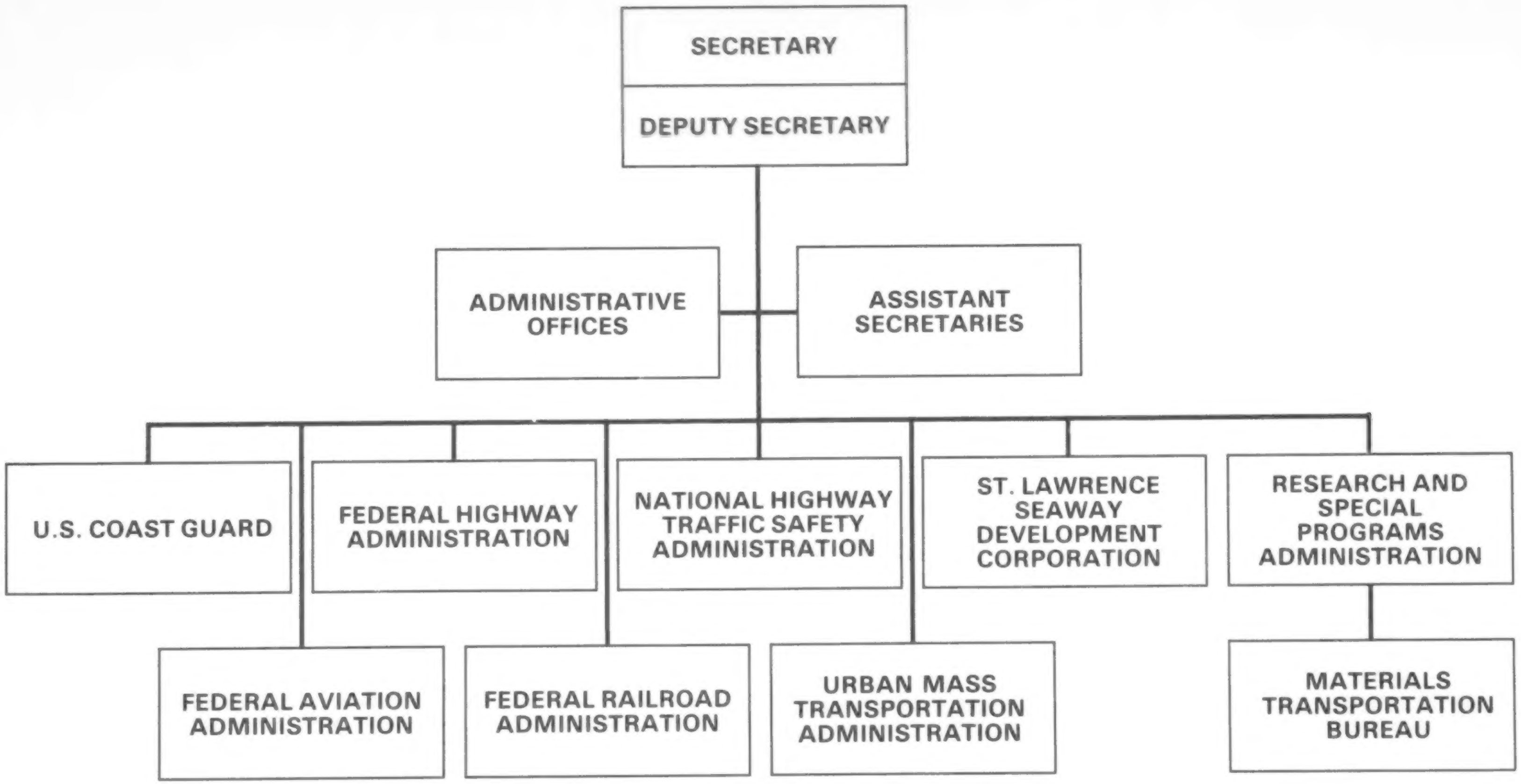
400 7th Street SW.
Washington, D.C. 20590

Locator: 202-426-4000
Information: 202-426-4000

The Department of Transportation (DOT) is responsible for issuing and enforcing regulations ensuring the safe transportation of hazardous materials by all modes of transport. Hazardous materials include, but are not limited to, articles used in industry and general commerce such as explosives, flammable gases and liquids, poisons, corrosives and radioactive materials, as well as other toxic substances.

There are two administrations within the Department which have responsibility for the development of regulations and other activities relating to transportation of hazard materials. The lead agency is the Materials Transportation Bureau (MTB) of DOT's Research and Special Programs Administration. The MTB is responsible for regulations governing all modes of transportation except bulk shipments by water. Regulations for bulk shipments by water are the responsibility of the United States Coast Guard. For the purposes of this publication, the two administrations--the Materials Transportation Bureau and the United States Coast Guard--will be covered in separate sections.

DEPARTMENT OF TRANSPORTATION
ORGANIZATIONAL CHART*


SECRETARY
DEPUTY SECRETARY
ADMINISTRATIVE OFFICES
ASSISTANT SECRETARIES
U.S. COAST GUARD
FEDERAL HIGHWAY ADMINISTRATION
NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION
ST. LAWRENCE SEAWAY DEVELOPMENT CORPORATION
RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
FEDERAL AVIATION ADMINISTRATION
FEDERAL RAILROAD ADMINISTRATION
URBAN MASS TRANSPORTATION ADMINISTRATION
MATERIALS TRANSPORTATION BUREAU

*NOTE: Only a partial organizational chart is shown to highlight (in gray) the two administrations within the Department which are involved in toxics-related activities.

MATERIALS TRANSPORTATION BUREAU

Research and Special Programs Administration
Department of Transportation
400 7th Street SW.
Washington, D.C. 20590

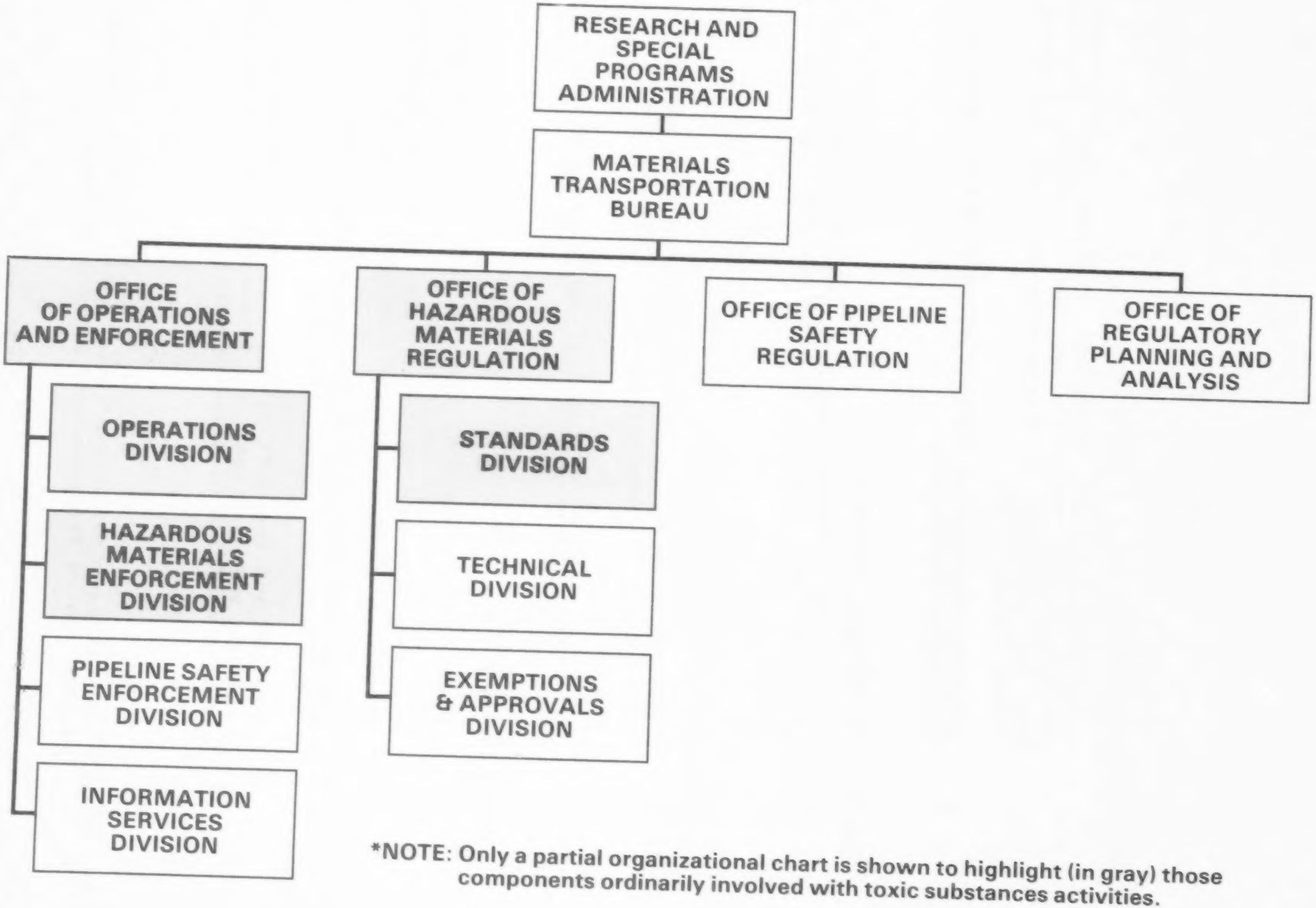
Locator: 202-426-4000
Information: 202-426-2301

Organization........................page 184
Statutory Authority...............page 187
Regulatory Development............page 188
Toxics-Related Activities..........page 189

In 1974, Congress enacted the Hazardous Materials Transportation Act which delegated broad authority to the Secretary of Transportation in all matters concerning the transportation of hazardous materials. In July 1975, the Secretary began to make the administrative changes that Congress authorized in the Act. By secretarial order, he created the Materials Transportation Bureau (MTB) and made it the lead agency in the Department of Transportation's (DOT) hazardous materials transportation safety program.

In the order creating the Bureau, the Secretary delegated to the Director of MTB the authority to issue all hazardous materials safety regulations except those relating to bulk transportation by water. (The U.S. Coast Guard, discussed in the next section, is responsible for all regulations and activities relating to bulk transportation by water.) To ensure Department-wide coordination under the new structure, the Director of MTB must consult with the other modal administrators within DOT (Federal Highway Administration [FHWA], Federal Aviation Administration [FAA], Federal Railroad Administration [FRA] and the U.S. Coast Guard) before issuing regulations on matters affecting them.

U.S. DEPARTMENT OF TRANSPORTATION
RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
MATERIALS TRANSPORTATION BUREAU
ORGANIZATION CHART*


RESEARCH AND SPECIAL PROGRAMS ADMINISTRATION
MATERIALS TRANSPORTATION BUREAU
OFFICE OF OPERATIONS AND ENFORCEMENT
OPERATIONS DIVISION
HAZARDOUS MATERIALS ENFORCEMENT DIVISION
PIPELINE SAFETY ENFORCEMENT DIVISION
INFORMATION SERVICES DIVISION
OFFICE OF HAZARDOUS MATERIALS REGULATION
STANDARDS DIVISION
TECHNICAL DIVISION
EXEMPTIONS & APPROVALS DIVISION
OFFICE OF PIPELINE SAFETY REGULATION
OFFICE OF REGULATORY PLANNING AND ANALYSIS

*NOTE: Only a partial organizational chart is shown to highlight (in gray) those components ordinarily involved with toxic substances activities.

ORGANIZATION*

OFFICE OF OPERATIONS AND ENFORCEMENT

- Plans and performs inspections, testing, registration, and enforcement functions necessary to assume compliance with MTB hazardous materials transportation and pipeline safety regulations.
- Develops analyses of impacts of proposed or existing regulatory activities.

Information Services Division

- Develops and conducts training and public programs for dissemination of safety information and standards requirements.

Hazardous Materials Enforcement Division

- Conducts inspections and investigations to ensure enforcement of hazardous materials transportation regulations.
- Processes hazardous material compliance actions.

OFFICE OF HAZARDOUS MATERIALS REGULATION

- Plans, recommends and develops a national regulatory program to protect against the risks to life and property inherent in the transportation of hazardous materials (other than bulk transport by water).
- Issues Notices of Proposed Rulemaking (NPRM), exemptions, and interpretations.
- Reviews and responds to requests for inconsistency rulings and nonpreemption determinations (in conjunction with the Office of Chief Counsel).

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

Standards Division

- Prepares hazardous materials transportation regulations for issuance or revision.
- Issues interpretations of standards.
- Maintains liaison with other Federal agencies and other organizations concerning hazardous materials standards.

Technical Division

- Provides technical evaluations of petitions for rulemaking and exemptions.
- Prepares technical reports on specific aspects related to the development of hazardous materials transportation regulations.

Exemptions and Approvals Division

- Evaluates applications for exemptions.
- Operates approvals and registration functions under the Hazardous Materials Regulations.

OFFICE OF REGULATORY PLANNING AND ANALYSIS

- Provides integrated planning evaluation of regulatory programs for MTB.
- Defines requirements for and manages the Hazardous Materials Information System.
- Establishes and maintains an MTB docket and information service for all hazardous materials and pipeline safety official matters.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone*	Mail Stop
Office of the Director	202-755-9260	DMT-1
Office of Operations and Enforcement	202-755-9247	DMT-10
Hazardous Materials Enforcement Division	202-755-5894	DMT-12
Information Services Division	202-426-2301	DMT-11
Office of Hazardous Materials Regulation	202-426-0656	DMT-20
Standards Division	202-426-2075	DMT-21
Technical Division	202-755-4906	DMT-22
Exemptions and Approvals Divisions	202-755-4962	DMT-23
Office of Regulatory Planning and Analysis	202-472-2648	DMT-60

*FTS numbers are the same

STATUTORY AUTHORITIES

Hazardous Materials Transportation Act

Public Law 93-633 49 U.S.C. § 1801

The Hazardous Materials Transportation Act (HMTA) was developed because of the many problems that had been encountered in the administration of other statutes concerning the transportation of hazardous materials (Dangerous Cargo Act, Transportation of Explosives Act, Federal Aviation Act, Federal Railroad Safety Act).

The goal of HMTA is to "improve the regulatory and enforcement authority of the Secretary of Transportation to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce."

Key Sections of Act--Toxics Focus

sec. 103	Defines "hazardous materials."
sec. 104	Authorizes the Secretary to designate materials as hazardous when the transportation of a particular quantity and form of a material may pose an "unreasonable risk" to health, safety, or property.
sec. 105	Requires the Secretary to develop regulations that govern any safety aspect of the transportation of hazardous materials.
sec. 106	Authorizes the Secretary to establish criteria for handling hazardous materials.
sec. 107	Provides for exemptions and exclusions from the Act.
sec. 111	Allows the Secretary to petition the courts for the suspension or restriction of the transportation of a hazardous material which poses an "imminent hazard."
sec. 112	Preempts State and local requirements that are inconsistent with the Act or any regulation issued under the Act.

Regulatory Options Available Under Statute

- Can require special packaging, handling, labeling, placarding, routing, or other actions necessary to ensure the safe transportation of hazardous materials.
- Can petition the courts to suspend or restrict the transportation of hazardous material which poses an imminent hazard.

REGULATORY DEVELOPMENT

REGULATORY PROCESS

1. A petition to issue, amend, or repeal a regulation is received or is proposed as a result of internal action.
2. All activity regarding the proposed rule must be coordinated with the modal administration affected by the rule (Federal Highway Administration (FHWA), Federal Aviation Administration (FAA), Federal Railroad Administration (FRA), U.S. Coast Guard (USCG)).
3. Depending on the complexity of the rule, the Bureau may publish an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register. Otherwise, a Notice of Proposed Rulemaking is published and comments are solicited.
4. All comments received as well as the recommendations of any technical advisory group established for the purpose of reviewing the rule are considered.
5. The Director may initiate any further rulemaking proceedings that he deems necessary.
6. The final rule is prepared, reviewed by the Chief Counsel (Research and Special Programs Administration) and then submitted to the Director for his consideration.
7. If the Director adopts the regulation, it is published in the Federal Register.

EXISTING REGULATIONS

Hazardous Materials Transportation Act Hazardous Materials Regulations	49 CFR 171-179 (Subchapter C)
Procedural Regulations	49 CFR 106-107

TOXICS-RELATED ACTIVITIES*

Compliance Enforcement Program

The Department's Compliance Enforcement Program has two main objectives: (1) to reduce the number of transportation incidents, and (2) to minimize the risk of catastrophic occurrences resulting from the violation of hazardous materials regulations. Each modal administration (FAA, FHWA, FRA, U.S. Coast Guard) retains inspection and enforcement authority over its modal carriers, while the MTB provides guidance and technical support to ensure uniformity in the interpretation and application of the regulation.

Research and Development Program

The Department utilizes the services of a number of Federal and private research organizations to supply the technical data needed to support the development, modification, compliance, and enforcement of hazardous materials regulations.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Chemical Coordination Staff.

UNITED STATES COAST GUARD

2100 Second Street SW
Washington, D.C. 20593

Locator: 202-426-4000
Information: 202-426-2158

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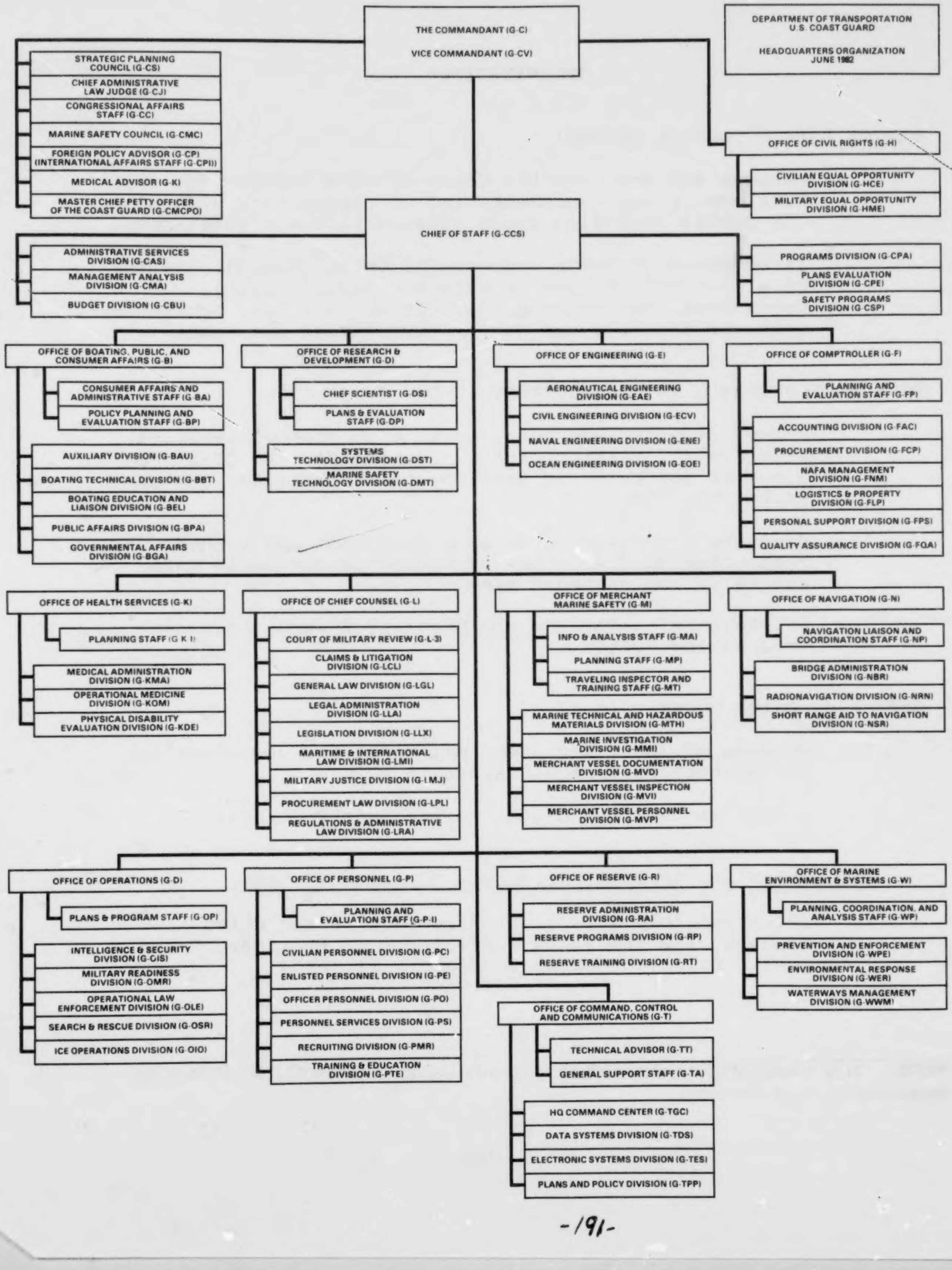
Regulatory Development..........Page 200
Toxics-Related Activities.......Page 201

The United States Coast Guard (USCG) has been involved with the transportation of hazardous materials since 1852 when the Steamship Inspection Act was passed. This Act specified that hazardous materials were to be stowed away from boilers on passenger vessels. The ensuing years saw the passage of a number of other Acts such as the Tank Vessel Act of 1936, which subjected tank vessels carrying bulk cargoes to various inspection, licensing, and operating requirements; and the Magnuson Act of 1950, which gave the Coast Guard authority regarding the supervision of cargo loading and storing, inspection of vessels, and control of ship movements under specified conditions.

The pollution prevention role of the Coast Guard was expanded with the passage of the Ports and Waterways Safety Act of 1972 as amended by the Port and Tanker Safety Act of 1978. This Act was designed to promote the safety of ports, harbors, waterfront areas, and navigable waters of the United States. There is also authority for enforcement of port safety under the Espionage Act (1917).

Currently, the Coast Guard has hazardous materials transportation and safety-related responsibilities under the Federal Water Pollution Control Act, 1972, as amended (the Clean Water Act amendments), the Outer Continental Shelf Lands Act, as amended 1978, the Deepwater Port Act (1974) and the Comprehensive Environmental Response, Compensation and Liability Act, 1980 (CERCLA).

UNITED STATES COAST GUARD


THE COMMANDANT (G-C)
VICE COMMANDANT (G-CV)
DEPARTMENT OF TRANSPORTATION U.S. COAST GUARD
HEADQUARTERS ORGANIZATION JUNE 1982
STRATEGIC PLANNING COUNCIL (G-CS)
CHIEF ADMINISTRATIVE LAW JUDGE (G-CJ)
CONGRESSIONAL AFFAIRS STAFF (G-CC)
MARINE SAFETY COUNCIL (G-CMC)
FOREIGN POLICY ADVISOR (G-CP) (INTERNATIONAL AFFAIRS STAFF (G-CPI))
MEDICAL ADVISOR (G-K)
MASTER CHIEF PETTY OFFICER OF THE COAST GUARD (G-CMCPO)
OFFICE OF CIVIL RIGHTS (G-H)
CIVILIAN EQUAL OPPORTUNITY DIVISION (G-HCE)
MILITARY EQUAL OPPORTUNITY DIVISION (G-HME)
CHIEF OF STAFF (G-CCS)
ADMINISTRATIVE SERVICES DIVISION (G-CAS)
MANAGEMENT ANALYSIS DIVISION (G-CMA)
BUDGET DIVISION (G-CBU)
PROGRAMS DIVISION (G-CPA)
PLANS EVALUATION DIVISION (G-CPE)
SAFETY PROGRAMS DIVISION (G-CSP)
OFFICE OF BOATING, PUBLIC, AND CONSUMER AFFAIRS (G-B)
CONSUMER AFFAIRS AND ADMINISTRATIVE STAFF (G-BA)
POLICY PLANNING AND EVALUATION STAFF (G-BP)
AUXILIARY DIVISION (G-BAU)
BOATING TECHNICAL DIVISION (G-BBT)
BOATING EDUCATION AND LIAISON DIVISION (G-BEL)
PUBLIC AFFAIRS DIVISION (G-BPA)
GOVERNMENTAL AFFAIRS DIVISION (G-BGA)
OFFICE OF RESEARCH & DEVELOPMENT (G-D)
CHIEF SCIENTIST (G-DS)
PLANS & EVALUATION STAFF (G-DP)
SYSTEMS TECHNOLOGY DIVISION (G-DST)
MARINE SAFETY TECHNOLOGY DIVISION (G-DMT)
OFFICE OF ENGINEERING (G-E)
AERONAUTICAL ENGINEERING DIVISION (G-EAE)
CIVIL ENGINEERING DIVISION (G-ECV)
NAVAL ENGINEERING DIVISION (G-ENE)
OCEAN ENGINEERING DIVISION (G-EOE)
OFFICE OF COMPTROLLER (G-F)
PLANNING AND EVALUATION STAFF (G-FP)
ACCOUNTING DIVISION (G-FAC)
PROCUREMENT DIVISION (G-FCP)
NAFA MANAGEMENT DIVISION (G-FNM)
LOGISTICS & PROPERTY DIVISION (G-FLP)
PERSONAL SUPPORT DIVISION (G-FPS)
QUALITY ASSURANCE DIVISION (G-FQA)
OFFICE OF HEALTH SERVICES (G-K)
PLANNING STAFF (G-K-1)
MEDICAL ADMINISTRATION DIVISION (G-KMA)
OPERATIONAL MEDICINE DIVISION (G-KOM)
PHYSICAL DISABILITY EVALUATION DIVISION (G-KDE)
OFFICE OF CHIEF COUNSEL (G-L)
COURT OF MILITARY REVIEW (G-L-3)
CLAIMS & LITIGATION DIVISION (G-LCL)
GENERAL LAW DIVISION (G-LGL)
LEGAL ADMINISTRATION DIVISION (G-LLA)
LEGISLATION DIVISION (G-LLX)
MARITIME & INTERNATIONAL LAW DIVISION (G-LMI)
MILITARY JUSTICE DIVISION (G-LMJ)
PROCUREMENT LAW DIVISION (G-LPL)
REGULATIONS & ADMINISTRATIVE LAW DIVISION (G-LRA)
OFFICE OF MERCHANT MARINE SAFETY (G-M)
INFO & ANALYSIS STAFF (G-MA)
PLANNING STAFF (G-MP)
TRAVELING INSPECTOR AND TRAINING STAFF (G-MT)
MARINE TECHNICAL AND HAZARDOUS MATERIALS DIVISION (G-MTH)
MARINE INVESTIGATION DIVISION (G-MMI)
MERCHANT VESSEL DOCUMENTATION DIVISION (G-MVD)
MERCHANT VESSEL INSPECTION DIVISION (G-MVI)
MERCHANT VESSEL PERSONNEL DIVISION (G-MVP)
OFFICE OF NAVIGATION (G-N)
NAVIGATION LIAISON AND COORDINATION STAFF (G-NP)
BRIDGE ADMINISTRATION DIVISION (G-NBR)
RADIONAVIGATION DIVISION (G-NRN)
SHORT RANGE AID TO NAVIGATION DIVISION (G-NSR)
OFFICE OF OPERATIONS (G-O)
PLANS & PROGRAM STAFF (G-OP)
INTELLIGENCE & SECURITY DIVISION (G-OIS)
MILITARY READINESS DIVISION (G-OMR)
OPERATIONAL LAW ENFORCEMENT DIVISION (G-OLE)
SEARCH & RESCUE DIVISION (G-OSR)
ICE OPERATIONS DIVISION (G-OIO)
OFFICE OF PERSONNEL (G-P)
PLANNING AND EVALUATION STAFF (G-P-1)
CIVILIAN PERSONNEL DIVISION (G-PC)
ENLISTED PERSONNEL DIVISION (G-PE)
OFFICER PERSONNEL DIVISION (G-PO)
PERSONNEL SERVICES DIVISION (G-PS)
RECRUITING DIVISION (G-PMR)
TRAINING & EDUCATION DIVISION (G-PTE)
OFFICE OF RESERVE (G-R)
RESERVE ADMINISTRATION DIVISION (G-RA)
RESERVE PROGRAMS DIVISION (G-RP)
RESERVE TRAINING DIVISION (G-RT)
OFFICE OF MARINE ENVIRONMENT & SYSTEMS (G-W)
PLANNING, COORDINATION, AND ANALYSIS STAFF (G-WP)
PREVENTION AND ENFORCEMENT DIVISION (G-WPE)
ENVIRONMENTAL RESPONSE DIVISION (G-WER)
WATERWAYS MANAGEMENT DIVISION (G-WWM)
OFFICE OF COMMAND, CONTROL AND COMMUNICATIONS (G-T)
TECHNICAL ADVISOR (G-TT)
GENERAL SUPPORT STAFF (G-TA)
HQ COMMAND CENTER (G-TGC)
DATA SYSTEMS DIVISION (G-TDS)
ELECTRONIC SYSTEMS DIVISION (G-TES)
PLANS AND POLICY DIVISION (G-TPP)

ORGANIZATION*

MARINE SAFETY COUNCIL (G-CMC)

- Manages and monitors the Coast Guard's program for the development and implementation of regulations affecting the public including those related to toxic substances.
- Is composed of seven members-The Chief Counsel, and the Chiefs of the Offices of Merchant Marine Safety, Operations, Engineering, Navigation, Boating, Public and Consumer Affairs, and Marine Environment and Systems.

OFFICE OF RESEARCH AND DEVELOPMENT (G-D)

- Plans, directs, and coordinates a program of research, development, testing, and evaluation for the Coast Guard aimed at improving or devising new techniques, methods, equipment, etc.
- Conducts a program to develop equipment and methods for responding to discharges of hazardous chemicals into waters of the United States.
- Develops and maintains the Chemical Hazards Response Information System.

OFFICE OF CHIEF COUNSEL (G-L)

- Renders advisory services, opinions, and decisions on all matters of a legal nature.
- Serves as Chairman of the Marine Safety Council.

Regulation and Administrative Law Division (G-LRA)

- Is responsible (under the direction of the Chief Counsel) for the legal sufficiency of the Coast Guard's public rules and other regulatory matters.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Reviews rules and regulations for their application to the Coast Guard.

Maritime and International Law Division

- Is responsible (under the direction of the Chief Counsel) for advisory services, opinions and decisions on all toxic and toxic-related matters of a legal nature.

OFFICE OF MERCHANT MARINE SAFETY (G-M)

- Oversees the program for prevention of marine casualties.
- Responsible for the inspection of merchant vessels for compliance with safety standards.

Marine Technical and Hazardous Materials Division (G-MTH)

- Initiates or reviews regulations relating to hazardous cargo containment, handling and storage.
- Studies data on toxicity and other hazards to determine the safety precautions necessary when handling dangerous cargo.
- Identifies and monitors research projects in hazardous material safety.
- Maintains liaison with other Federal agencies and represents the Coast Guard on advisory committees involved in regulating hazardous material and dangerous cargo.
- Administers a program for certification of foreign chemical and gas tanker vessels.

Cargo and Hazards Branch (G-MTH-3)

- Conducts the hazard analysis of chemicals prior to authorization for shipment in bulk.

- Initiates research to assign toxicity, flammability and reactivity hazards to chemicals being or likely to be carried by water, and to minimize crew exposure to hazardous materials during transport and transfer operations.

- Reviews toxicological data from a variety of sources for possible incorporation into Coast Guard regulations.

Merchant Vessel Inspection Division (G-MVI)

- Develops and enforces safety standards for vessels.

- Issues standards for the protection of merchant seamen from exposure to chemicals.

Merchant Vessel Personnel Division (G-MVP)

- Establishes standards for licensing of U.S. merchant seamen and levels of staffing for U.S. vessels.

- Is currently upgrading the qualifications for tankerman endorsement to more fully address operations of hazardous materials.

OFFICE OF MARINE ENVIRONMENT AND SYSTEMS (G-W)

- Administers a coordinated Coast Guard environmental program.

- Manages a comprehensive ports and waterways system encompassing all aspects of marine transportation except vessel safety.

Environmental Response Division (G-WER)

- Provides Department of Transportation membership on the National Response Team.

- Plans, coordinates, implements, and monitors a program to control pollution of the marine environment in accordance with statutory requirements and the policies of the Department of Transportation.

Pollution Response Branch (G-WER-2)

- Plans, develops, and implements the Coast Guard Program for pollution removal from the marine environment.

- Manages and coordinates the National Strike Force.

Environmental Coordination Branch (G-WER-3)

- Establishes and maintains liaison with appropriate Headquarters and Departmental offices to ensure coordination of Coast Guard's environmental program.

- Represents the Coast Guard at meetings involving governmental agencies, the public and private sectors, and international organizations regarding general environmental matters.

Port and Environmental Safety Division (G-WPE)

- Manages the Coast Guard Port Safety/Security Program for ports and navigable waterways of the United States.

Port and Environmental Safety Enforcement Branch (G-WPE-1)

- Develops, manages, and monitors functions administered by the Captains of the Port and Port Safety stations including the administration of dangerous cargo regulations.

- Directs the Coast Guard's program to prevent and investigate pollution discharges into the marine environment.

- Plans, develops, and implements Coast Guard programs to detect pollution in the marine environment.

Environmental Impact Branch (G-WP-4)

- Plans, directs, and monitors a Coast Guard program to comply with the National Environmental Policy Act of 1969 (NEPA) and related legislation.

- Plans, directs, and monitors a Coast Guard program concerned with the abatement of pollution from Coast Guard facilities (vessels, vehicles, aircraft, structures, and shore stations).

National Response Center Staff (G-TGC-2)

- Manages and operates the National Response Center to support the National Response Team in accordance with the National Oil and Hazardous Substances Pollution Contingency Plan.

Division/Office	Phone*	Mail Stop
U.S.C.G./EPA Liaison Officer	202-755-0770	-
Marine Safety Council	202-426-1477	(G-CMC)
Office of Research and Development	202-426-1040	(G-D)
Office of Chief Counsel	202-426-1616	(G-L)
Regulations and Administrative Law Division	202-426-1534	(G-LRA)
Maritime & International Law Division	202-426-1527	(G-LMI)
Office of Merchant Marine Safety	202-426-2200	(G-M)
Marine Technical and Hazardous Materials Division	202-426-2167	(G-MTH)
Cargo and Hazards Branch	202-426-1577	(G-MTH-3)
Merchant Vessel Inspection Division	202-426-2178	(G-MVI)
Merchant Vessel Personnel Division	202-426-1500	(G-MVP)
Office of Marine Environment and Systems	202-426-2007	(G-W)
Environmental Response Division	202-426-2010	(G-WER)

Pollution Response Branch	202-426-9568	(G-WER-2)
Environmental Coordination Branch	202-426-9573	(G-WER-3)
Information Analysis Branch	202-426-9571	(G-WER-4)
National Response Center Staff	202-426-2675	(G-TGC-2)
Environmental Impact Branch	202-426-3300	(G-WP-4)
Port and Environmental Safety Division	202-426-1934	(G-WPE)
Port and Environmental Safety Enforcement Branch	202-755-7917	(G-WPE-1)

*FTS numbers are the same

STATUTORY AUTHORITIES

Port and Tanker Safety Act
Public Law 95-474: 46 U.S.C.§391a (vessels)
33 U.S.C.§1221 (ports)

The Port and Tanker Safety Act is designed to provide adequate protection of the Nation's coastal areas and marine environment. It allows the Secretary of the Department in which the Coast Guard is operating (currently the Department of Transportation) to set standards of vessel design and safety and to establish measures for the safe transportation of potentially dangerous cargoes, including toxic substances. The Secretary is authorized to investigate any incidents involving damage to marine areas or ecosystems, and to ensure compliance with the provisions of the Act.

Key Sections of Act - Toxics Focus

33 U.S.C.1223, 1225	Authorizes Secretary to establish regulations and procedures for the safe storage and transportation of toxic substances on vessels in navigable U.S. waters.
33 U.S.C.1227	Permits Secretary to investigate accidents causing damage to the environmental quality of ports, harbors, or other coastal areas.
33 U.S.C.1231	Allows Secretary to establish regulations and other standards to enforce the Act.
46 U.S.C.391a	Defines and sets standards for the transport of liquid cargo in bulk.
46 U.S.C.391a(6)	Permits Secretary to establish rules governing vessel design and maintenance.
46 U.S.C.391a(6)	Provides for consultation with other Federal agencies involved in marine environmental protection.

Regulatory Options Available Under Statute

- Control vessel traffic and operation
- Establish vessel safety requirements
- Set standards for transport of dangerous cargoes
- Limit vessel activity in defined waterfront safety zones
- Restrict the transportation of hazardous materials (in bulk cargo from navigable waters)
- Ban the transportation of hazardous materials in bulk cargo from navigable waters

REGULATORY DEVELOPMENT

REGULATORY PROCESS

1. All regulations projects are proposed by the appropriate program office. The proposal is forwarded to the Marine Safety Council for its approval.

2. All rulemaking is conducted pursuant to the informal rulemaking procedures of the Administrative Procedure Act [5 U.S.C.551-553]. The advance notice of proposed rulemaking, notice of proposed rulemaking, and supplemental notice of proposed rulemaking are utilized. Public hearings are held only for the more important rulemakings.

3. The majority of final rules are cleared through the program office. For significant rulemaking, clearance by the Commandant and Secretary of the Department of Transportation is required.

4. All rules dealing with toxic substances are subject to the clearance provisions of Executive Order 12291 of February 17, 1981.

EXISTING REGULATIONS

Port and Tanker Safety Act
(ports) 33 U.S.C.§1221 33 CFR 126, 160-165
(vessels) 46 U.S.C.§391a 33 CFR 157, 164: 46 CFR 30-40, 150-154

TOXICS-RELATED ACTIVITIES*

Marine Transport of Hazardous Cargoes - General

Statute: 33 U.S.C.§1321; 46 U.S.C.§391a, 49 U.S.C.§1803

Regulations: 46 CFR 146 thru 154 (Subchapter "N" and "O")

Responsible Office: G-MTH (Marine Technical and Hazardous Materials Division)

Description:

46 CFR SUBCHAPTER N - DANGEROUS CARGOES

a.	46 CFR 147	Regulations governing use of dangerous articles as ships stores and supplies on board vessels.
b.	46 CFR 147A	Interim regulations for shipboard fumigation.
c.	46 CFR 148	Carriage of solid hazardous materials in bulk.

46 CFR SUBCHAPTER O - CERTAIN BULK DANGEROUS CARGOES

a.	46 CFR 150	Compatibility of cargoes and operational requirements for bulk liquid hazardous waste cargoes.
b.	46 CFR 151	Regulates the carriage of bulk liquid hazardous cargoes by barge.
c.	46 CFR 153	Regulates the carriage of hazardous liquids by tank vessel.
d.	49 CFR 154	Regulates carriage of liquified gases by tank vessels.

Transfer Operations Involving Bulk Liquid Hazardous Substances

Statute 33 U.S.C.§1321

Regulations: 33 CFR 126, 154, 155, 156; 40 CFR 117

Responsible Office: G-WER (Marine Environmental Protection Division),
G-WPE (Port Safety and Law Enforcement Division)

Description: 40 CFR 117 designates the hazardous substances regulated under this program (not all listed permitted to be shipped in bulk).

New Items: Streamlining, consolidation, and addition of hazardous substances to the present regulations (which speak only to oil) are in progress. Development of a comprehensive regulatory package to address transfer operations of hazardous substances.

Arrival and Departure of Vessels Carrying Certain Dangerous Cargoes

Statute: 33 U.S.C.§§1223, 1228; 46 U.S.C.§391a

Regulations: 33 CFR 161

Responsible Office: G-WPE (Port Safety and Law Enforcement Division)

Description: 33 CFR 161; requires advance notice of the arrival or departure of vessels carrying "cargoes of particular hazard" and defines cargoes of particular hazard.

New Items:

a. To permit advance contingency planning by persons responsible for safety of ports, prior to port entry, vessels will be required to report conditions which may adversely affect the operation of the vessel.

b. IMO is studying additional requirements for vessels in international waters to report marine casualties to the nearest country. Regulations implementing the IMO Convention will be added to 33 CFR 151 upon ratification.

c. These regulations are being shifted to Subpart C, 33 CFR 160. The cargoes covered are being reviewed for deletions or additions.

Ocean Dumping Surveillance

Statute: 16 U.S.C.§1431; 33 U.S.C.§§1401, 1417, 1418

Regulations: 33 CFR 158; 40 CFR 220 thru 229

Responsible Office: G-WER (Environmental Response Division)

Description:

a. 40 CFR 220 thru 229 describe the permit system established by EPA to regulate ocean dumping of all materials except dredged material.

b. 33 CFR 323-325 describes the permit system established by the Army Corps of Engineer (ACOE) to regulate ocean dumping of dredged material.

New Items: Dumping surveillance regulations were proposed during December 1979.

Inspection of Foreign Flag Tank Ships

Statute: 33 U.S.C.§1321; 46 U.S.C.§391a; 49 U.S.C.§1803

Regulation: 46 CFR 2

Responsible Office: G-MVI (Merchant Vessel Documentation Division)

Description: The series of tank explosions which occurred in the winter of 1976-77 prompted an immediate and singularly successful unilateral inspection program of cargo-handling systems on foreign flag tank ships entering U.S. ports.

Response to Spills of Oil or Hazardous Substances

Statute: 33 U.S.C.§1321 (FWPCA); 42 U.S.C.§9615 (CERCLA)

Regulations: 33 U.S.C. 153; 40 CFR 110, 116, 117, 300 See 37 F.R. 31180, July 16, 1982

Responsible Office: G-WER (Environmental Response Division)

Description:

a. 40 CFR 110 defines oil or "harmful quantity".
b. 40 CFR 116 designates hazardous substances.
c. 40 CFR 117 defines reportable quantities of hazardous substances.
d. 40 CFR 300 is the Revised National Contingency Plan.
e. 33 CFR 153 is the USCG implementation of the Clean Water Act in regard to response activity under the National Contingency Plan, and management of the pollution revolving fund.

New Items:

1. The National Contingency Plan was revised on March 19, 1980, to conform to the Clean Water Act (as amended in 1977). See 45 FR 17832.
2. The National Contingency Plan was revised on July 16, 1982 (37 F.R. 31180) pursuant to section 105 of CERCLA and became effective on December 10, 1982.
3. E.O. 11735 was amended on May 10, 1983 by E.O. 12418. The amendment concerns delegation of the authority to respond to substantial threats.

ENVIRONMENTAL PROTECTION AGENCY

401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-4361

EPA was created through an executive reorganization plan designed to consolidate certain Federal Government environmental activities into a single agency. The plan (Reorganization Plan No. 3 of 1970) was sent by the President to Congress on July 9, 1970, and EPA was established as an Independent Agency in the Executive Branch on December 2, 1970.

EPA was formed by combining 15 components from 5 departments and independent agencies. Water quality responsibilities were transferred from the Interior Department (the Federal Water Quality Administration) and the (former) Department of Health, Education, and Welfare* (the Bureau of Water Hygiene). Other activities transferred from HEW included the National Air Pollution Control Administration and the Bureau of Solid Waste Management.

In addition, EPA acquired the Department of Agriculture's authority to register pesticides and to regulate their use; the Food and Drug Administration's authority to set tolerance levels for pesticides which occur in or on food and to monitor compliance with those limits; and a portion of the Department of Interior's pesticides research program.

Finally, EPA assumed some of the authorities of the former Atomic Energy Commission and HEW for setting environmental radiation protection standards. The Agency also absorbed the duties of the Federal Radiation Council.

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*As of May 4, 1980, HEW was divided into two new departments--the Department of Health and Human Services and the Department of Education.

Organizationally, EPA is headed by an Administrator, who is supported by a Deputy Administrator and six Assistant Administrators (see chart). Three of the Assistant Administrators are responsible for "functionalized" activities, i.e., activities which cut across all media programs. These activities are planning and management, enforcement, and research and development. The remaining program activities have been grouped under three other Assistant Administrators on a media or pollutant basis, e.g., water pollution, air pollution, solid waste, toxic substances, etc. The activities carried out by these Offices are primarily policy development, preparation and promulgation of regulations, and support and evaluation of regional activities.

Eight Offices within EPA are highlighted in this publication. They are the Office of Pesticide Programs and the Office of Toxic Substances which are located within the Office of Pesticides and Toxic Substances; the Office of Water Regulations and Standards and the Office of Drinking Water, located within the Office of Water; the Office of Emergency and Remedial Response and the Office of Solid Waste located within the Office of Solid Waste and Emergency Response; and the Offices of Air Quality Planning and Standards and Mobile Sources* which are part of the Office of Air, Noise, and Radiation.

Included in this introductory section on EPA is a description of the regulatory development process within the Agency. Since this process is used by all of the EPA Offices, it was decided to place the description here and refer to it in the Regulatory Development Section of each Office.

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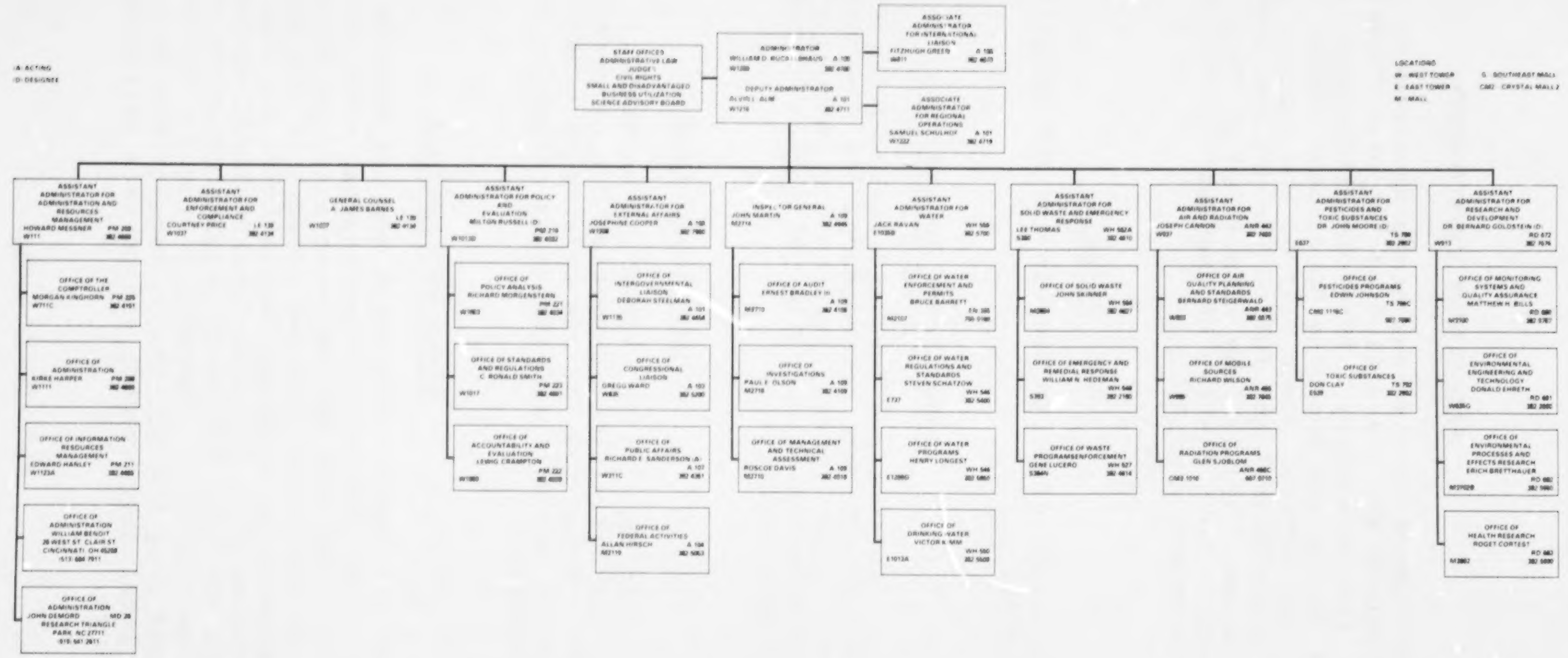
*NOTE: These two Offices are treated in one section, whereas the other Offices are developed in separate sections.

ORGANIZATION CHART
(INCLUDING NAMES, MAIL CODES, ROOMS AND TELEPHONE NUMBERS)
U.S. ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460


(A) ACTING
(D) DESIGNEE
STAFF OFFICES
ADMINISTRATIVE LAW JUDGES
CIVIL RIGHTS
SMALL AND DISADVANTAGED BUSINESS UTILIZATION
SCIENCE ADVISORY BOARD
ADMINISTRATOR
WILLIAM D. RUCKELSHAUS A 100
W1200 382 4700
DEPUTY ADMINISTRATOR
ALVIN L. ALM A 101
W1216 382 4711
ASSOCIATE ADMINISTRATOR FOR INTERNATIONAL LIAISON
FITZHUGH GREEN A 106
W811 382 4870
ASSOCIATE ADMINISTRATOR FOR REGIONAL OPERATIONS
SAMUEL SCHULHOF A 101
W1222 382 4719
LOCATIONS
W - WEST TOWER
E - EAST TOWER
M - MALL
S - SOUTHEAST MALL
CM2 - CRYSTAL MALL 2
ASSISTANT ADMINISTRATOR FOR ADMINISTRATION AND RESOURCES MANAGEMENT
HOWARD MESSNER PM 208
W111 382 4600
OFFICE OF THE COMPTROLLER
MORGAN KINGHORN PM 225
W711C 382 4151
OFFICE OF ADMINISTRATION
KIRKE HARPER PM 208
W1111 382 4600
OFFICE OF INFORMATION RESOURCES MANAGEMENT
EDWARD HANLEY PM 211
W1123A 382 4465
OFFICE OF ADMINISTRATION
WILLIAM BENOIT
26 WEST ST. CLAIR ST
CINCINNATI, OH 45268
(513) 684 7911
OFFICE OF ADMINISTRATION
JOHN DEMORD MD 20
RESEARCH TRIANGLE PARK, NC 27711
(919) 541 2611
ASSISTANT ADMINISTRATOR FOR ENFORCEMENT AND COMPLIANCE
COURTNEY PRICE LE 133
W1037 382 4134
GENERAL COUNSEL
A. JAMES BARNES LE 130
W1037 382 4136
ASSISTANT ADMINISTRATOR FOR POLICY AND EVALUATION
MILTON RUSSELL (D) PM 219
W1013D 382 4032
OFFICE OF POLICY ANALYSIS
RICHARD MORGENSTERN PM 221
W1003 382 4034
OFFICE OF STANDARDS AND REGULATIONS
C. RONALD SMITH PM 223
W1017 382 4001
OFFICE OF ACCOUNTABILITY AND EVALUATION
LEWIS CRAMPTON PM 222
W1000 382 4028
ASSISTANT ADMINISTRATOR FOR EXTERNAL AFFAIRS
JOSEPHINE COOPER A 100
W1308 382 7960
OFFICE OF INTERGOVERNMENTAL LIAISON
DEBORAH STEELMAN A 101
W1135 382 4454
OFFICE OF CONGRESSIONAL LIAISON
GREGG WARD A 103
W820 382 5200
OFFICE OF PUBLIC AFFAIRS
RICHARD E. SANDERSON (A) A 107
W311C 382 4361
OFFICE OF FEDERAL ACTIVITIES
ALLAN HIRSCH A 104
M2119 382 5053
INSPECTOR GENERAL
JOHN MARTIN A 109
M2714 382 4945
OFFICE OF AUDIT
ERNEST BRADLEY III A 109
M2710 382 4106
OFFICE OF INVESTIGATIONS
PAUL E. OLSON A 109
M2718 382 4109
OFFICE OF MANAGEMENT AND TECHNICAL ASSESSMENT
ROSCOE DAVIS A 109
M2710 382 4018
ASSISTANT ADMINISTRATOR FOR WATER
JACK RAVAN WH 556
E1030 382 5700
OFFICE OF WATER ENFORCEMENT AND PERMITS
BRUCE BARRETT EN 335
M2107 755 0100
OFFICE OF WATER REGULATIONS AND STANDARDS
STEVEN SCHATZOW WH 546
E737 382 5400
OFFICE OF WATER PROGRAMS
HENRY LONGEST WH 546
E1209G 382 5850
OFFICE OF DRINKING WATER
VICTOR KIMM WH 550
E1013A 382 5500
ASSISTANT ADMINISTRATOR FOR SOLID WASTE AND EMERGENCY RESPONSE
LEE THOMAS WH 562A
S360 382 4610
OFFICE OF SOLID WASTE
JOHN SKINNER WH 564
M2804 382 4627
OFFICE OF EMERGENCY AND REMEDIAL RESPONSE
WILLIAM N. HEDEMAN WH 548
S393 382 2180
OFFICE OF WASTE PROGRAMS ENFORCEMENT
GENE LUCERO WH 527
S384N 382 4814
ASSISTANT ADMINISTRATOR FOR AIR AND RADIATION
JOSEPH CANNON ANR 443
W937 382 7400
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
BERNARD STEIGERWALD ANR 443
W933 382 5575
OFFICE OF MOBILE SOURCES
RICHARD WILSON ANR 455
W935 382 7645
OFFICE OF RADIATION PROGRAMS
GLEN SJOBLOM ANR 458C
CM2 1016 557 9710
ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES
DR. JOHN MOORE (D) TS 788
E637 382 2902
OFFICE OF PESTICIDES PROGRAMS
EDWIN JOHNSON TS 766C
CM2 1115C 557 7090
OFFICE OF TOXIC SUBSTANCES
DON CLAY TS 792
E539 382 3813
ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT
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OFFICE OF MONITORING SYSTEMS AND QUALITY ASSURANCE
MATTHEW H. BILLS RD 680
M3700 382 5767
OFFICE OF ENVIRONMENTAL ENGINEERING AND TECHNOLOGY
DONALD EHRETH RD 681
W605G 382 2600
OFFICE OF ENVIRONMENTAL PROCESSES AND EFFECTS RESEARCH
ERICH BRETTHAUER RD 682
M3702B 382 5950
OFFICE OF HEALTH RESEARCH
ROGET CORTESI RD 683
M3802 382 5900

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REGULATORY DEVELOPMENT

At the onset of the regulatory development process, all new EPA regulations are classified as "Major," "Significant," or "Minor." (See Figure 1). This classification is done by the Office of Policy and Resource Management (OPRM) in consultation with the lead office. Over half of the current regulations are labeled "Significant" and follow the uniform development process outlined below. Regulations classified as "Major" follow that same process. Both classes of regulations include provisions for public review and comment.

Chart 1

Definitions of Terms Used in the EPA Regulatory Development Process.

Significant Regulations

All regulations are presumed to be Significant if there are important economic consequences for the public, important public health issues, inter-media issues, effects on the administration or operation of other offices or broad geographic effects.

Major Regulations

A regulation will be classified as Major if it is likely to meet the definition in Section One of Executive Order 12291. Major regulations require an economic impact analysis and will receive extra attention from senior Agency management.

Minor Regulations

These are regulations which are not subject to formal regulatory development procedures. They include: regulations that are administrative or procedural in nature and do not affect certain aspects of EPA programs; minor amendments to existing regulations; regulatory actions resulting from detailed Congressional mandates; regulations which the lead office Assistant Administrator designated as not sufficiently important to require formal development procedures; EPA actions on regulations developed by State and local governments; and certain pesticide-related actions.

Lead Office

The Assistant Administrator for the relevant program (the Office of Air, Noise, and Radiation, the Office of Pesticides and Toxic Substances, the Office of Water, and the Office of Solid Waste and Emergency Response) has the lead responsibility for initiating and writing most new regulations.

Senior Management

This group includes the Administrator, Deputy Administrator, and Assistant Administrators.

Work Groups

This is a group of specialists drawn from various offices within EPA to advise and assist the lead office in preparing each regulation and its support documents.

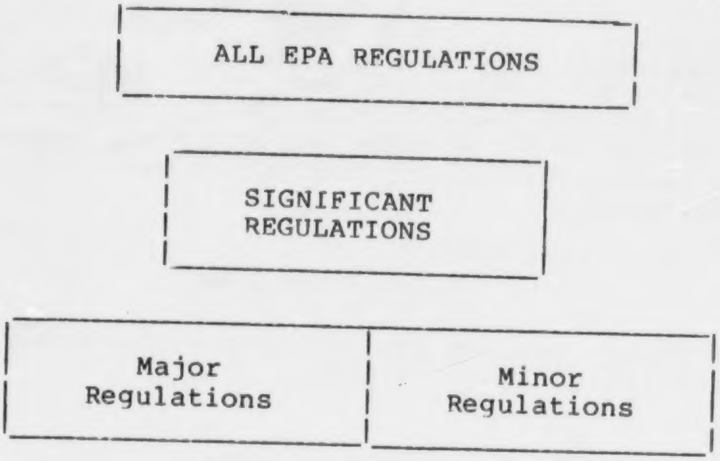
Steering Committee

This is a continuing group representing the six Assistant Administrators. It oversees the mechanics of the process and conducts the first internal review of materials prepared by the lead office.

Red Border Review

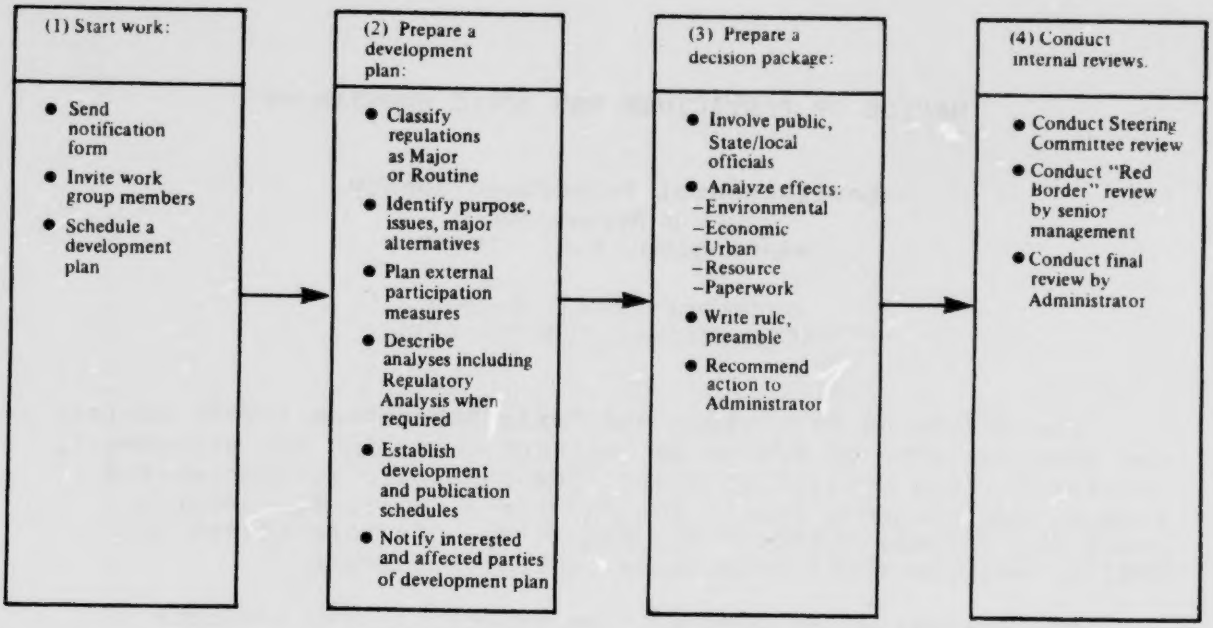
This is an internal review by the offices of two Assistant Administrators (Office of Policy and Resource Management and Office of Legal and Enforcement Counsel). Any program or Regional Office may be included if they express concern about a particular review.

Figure 1. Priority Classification for EPA Regulations


ALL EPA REGULATIONS
SIGNIFICANT REGULATIONS
Major Regulations
Minor Regulations

Regulations are produced in a multistage process: (1) approval stage, in which the lead office submits a start action request to OPRM, (2) preparation of a development plan, (3) preparation of a decision package, which also includes writing the preamble and regulation, and (4) conducting a three-part internal review. Each regulation goes through Steering Committee and Red Border reviews twice, first as a proposal and again as a final. The regulatory development process within EPA is summarized in Figure 2.

Figure 2. Stages in the Development of Significant EPA Regulations


(1) Start work:
Send notification form
Invite work group members
Schedule a development plan
(2) Prepare a development plan:
Classify regulations as Major or Routine
Identify purpose, issues, major alternatives
Plan external participation measures
Describe analyses including Regulatory Analysis when required
Establish development and publication schedules
Notify interested and affected parties of development plan
(3) Prepare a decision package:
Involve public, State/local officials
Analyze effects:
–Environmental
–Economic
–Urban
–Resource
–Paperwork
Write rule, preamble
Recommend action to Administrator
(4) Conduct internal reviews.
Conduct Steering Committee review
Conduct "Red Border" review by senior management
Conduct final review by Administrator

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

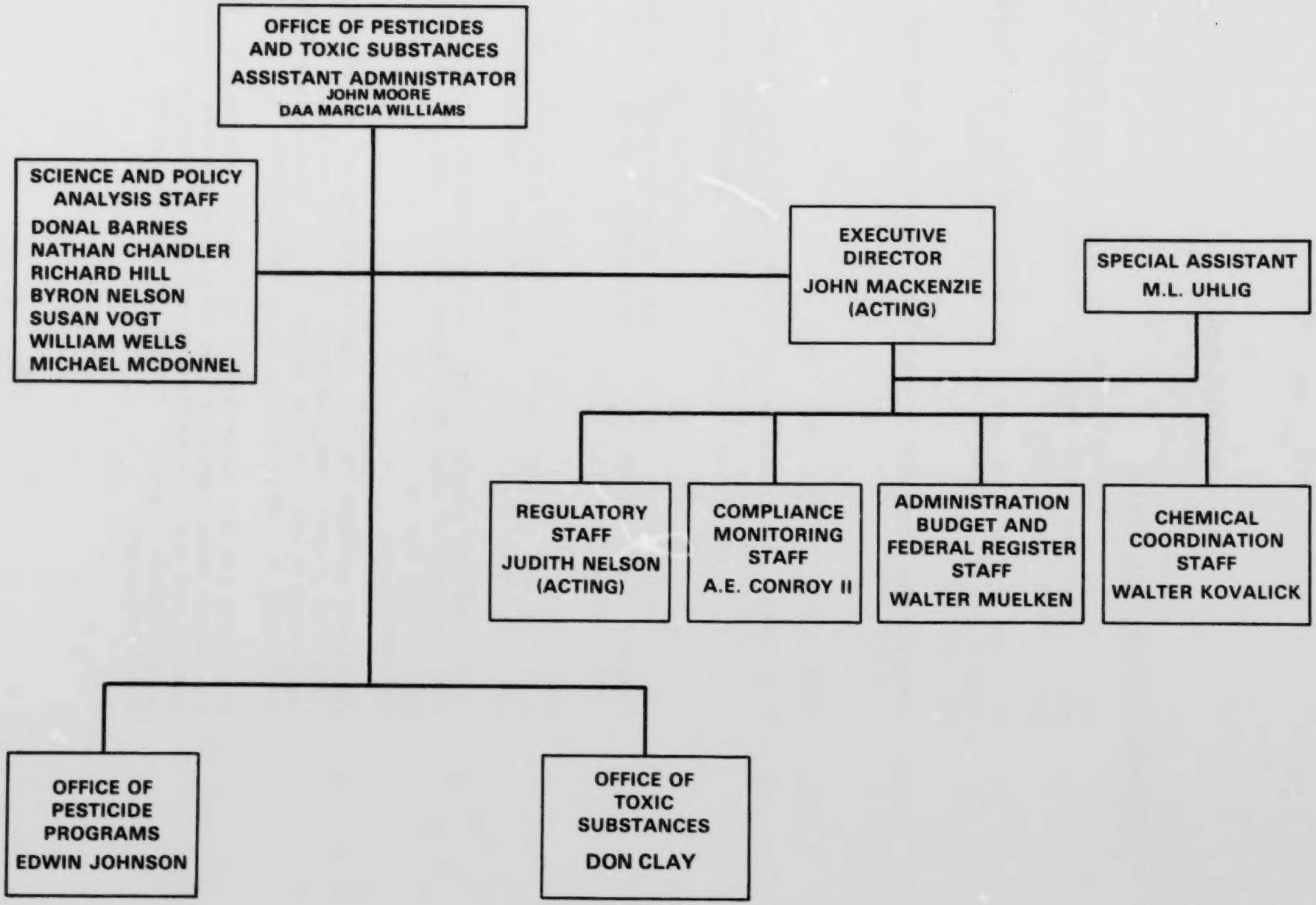
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-755-2673
Information: 202-755-0720

The Office of Pesticides and Toxic Substances (OPTS) advises the Administrator of EPA on all matters regarding the assessment, regulation, and control of pesticides and toxic substances and manages the Agency's pesticides and toxic substances program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA).

The activities of OPTS will be treated in two separate sections of this directory. One section will focus on the Office of Pesticide Programs which handles all Agency activities under FIFRA. The other section will concentrate on the Office of Toxic Substances which is responsible for EPA activities under TSCA.

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF THE ASSISTANT ADMINISTRATOR



OFFICE OF PESTICIDES
AND TOXIC SUBSTANCES
ASSISTANT ADMINISTRATOR
JOHN MOORE
DAA MARCIA WILLIAMS

SCIENCE AND POLICY
ANALYSIS STAFF
DONAL BARNES
NATHAN CHANDLER
RICHARD HILL
BYRON NELSON
SUSAN VOGT
WILLIAM WELLS
MICHAEL MCDONNEL

EXECUTIVE
DIRECTOR
JOHN MACKENZIE
(ACTING)

SPECIAL ASSISTANT
M.L. UHLIG

REGULATORY
STAFF
JUDITH NELSON
(ACTING)

COMPLIANCE
MONITORING
STAFF
A.E. CONROY II

ADMINISTRATION
BUDGET AND
FEDERAL REGISTER
STAFF
WALTER MUELKEN

CHEMICAL
COORDINATION
STAFF
WALTER KOVALICK

OFFICE OF
PESTICIDE
PROGRAMS
EDWIN JOHNSON

OFFICE OF
TOXIC
SUBSTANCES
DON CLAY

ORGANIZATION

Chemical Coordination Staff

- Establishes policies and procedures for the coordination and integration of Agency and Federal activities concerning toxic substances.
- Creates and analyses chemical and industry information data bases for integration of Agency chemical activities.
- Manages the Chemical Substances Information Network (CSIN).

Chemical Activities Coordination Group

- Identifies and investigates toxic substances activities within EPA needing integration and coordinates regulatory and other activities with appropriate groups.
- Conducts studies and analyses of Agency and other Federal agencies' criteria and plans for ordering and ranking toxic chemicals for assessment, technical evaluation, and regulation.
- Recommends chemical priorities for action, as well as policies and procedures to integrate Agency toxic substances activities to the Assistant Administrator.
- Evaluates EPA statutes in terms of policy consistency and efficacy of implementation with regard to integrated approaches for chemical information collection and dissemination.
- Develops procedures for implementation of section 9 of TSCA for identifying, determining and making recommendations for use of the most appropriate Federal authority for regulating toxic substances.
- Analyzes issues regarding chemicals of concern to the Assistant Administrator and conducts special cross-agency projects regarding chemicals of concern to the Deputy Administrator, Associate and Assistant Administrators.

- Participates in the development of Agency legislative packages to enhance toxic substances integration.

- Provides technical support to Regional Offices to ensure consistent approaches to chemical problems; monitors section 28 State grants program; and provides technical assistance to states regarding available information and analyses of toxic chemicals as well as concepts for integrated approaches for chemicals management across agencies at the State level.

Chemical Information Analysis Group

- Screens and evaluates EPA and other Federal activities and toxic-related data bases to prepare technical analyses, guidance documents, and other toxics integration mechanisms.

- Develops toxics integration data bases where there are critical needs for management information on cross-agency activities on chemicals.

- Maintains and updates such data bases to allow real-time assessment of technical, scientific and regulatory activities across the Agency.

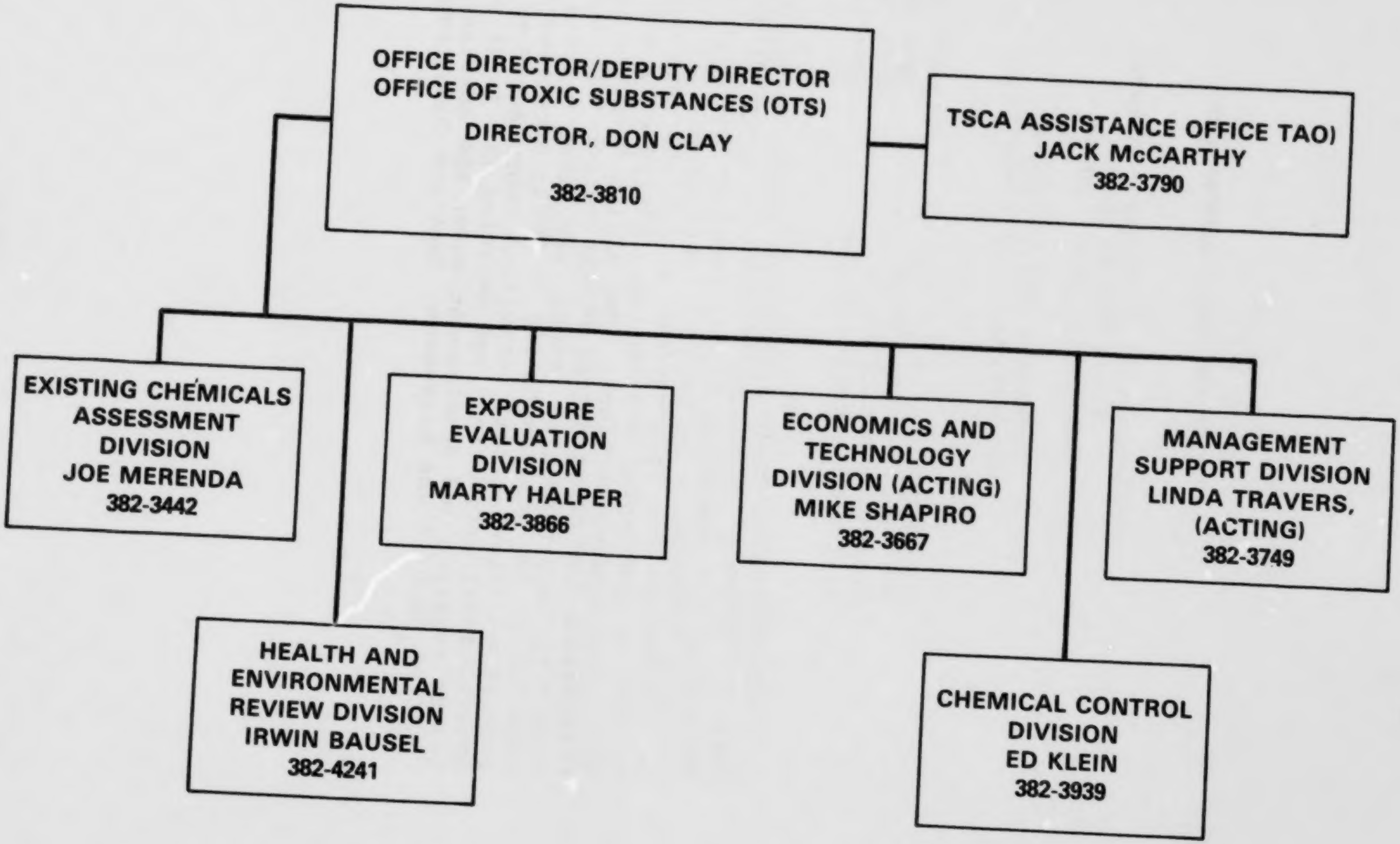
- Routinely recommends opportunities for further Agency coordination based upon analyses of such data bases.

Chemical Substances Information Network Group

- Co-chairs and provides staff support to the Interagency Toxic Substances Data Committee established under TSCA section 10(b).

- Manages the development and implementation of the Chemical Substances Information Network (CSIN) to collect, disseminate, and ensure more cost-effective use of toxicological and other scientific data.

OFFICE OF TOXIC SUBSTANCES
ORGANIZATIONAL CHART



OFFICE DIRECTOR/DEPUTY DIRECTOR
OFFICE OF TOXIC SUBSTANCES (OTS)
DIRECTOR, DON CLAY
382-3810

TSCA ASSISTANCE OFFICE TAO)
JACK McCARTHY
382-3790

EXISTING CHEMICALS ASSESSMENT DIVISION
JOE MERENDA
382-3442

EXPOSURE EVALUATION DIVISION
MARTY HALPER
382-3866

ECONOMICS AND TECHNOLOGY DIVISION (ACTING)
MIKE SHAPIRO
382-3667

MANAGEMENT SUPPORT DIVISION
LINDA TRAVERS, (ACTING)
382-3749

HEALTH AND ENVIRONMENTAL REVIEW DIVISION
IRWIN BAUSEL
382-4241

CHEMICAL CONTROL DIVISION
ED KLEIN
382-3939

OFFICE OF TOXIC SUBSTANCES

Environmental Protection Agency
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Locator: 202-755-2673
Information: 202-755-0720

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Toxics-Related Activities........page 229

The Office of Toxic Substances (OTS), as mandated by the Toxic Substances Control Act (TSCA), is responsible for developing and operating Agency programs and policies for new and existing chemicals. In each of these areas, the Office Director is responsible for information collection, data development, health, environmental and economic assessment, and negotiated or regulatory control actions. The Office Director is also responsible for coordinating communication with the industrial community, environmental groups, and other parties on matters relating to the implementation of TSCA; providing technical support to international activities coordinated by the Office of International Activities; and managing the joint planning of the toxics research and development under the auspices of the Chemical Testing and Assessment Research Committee (CTARC).

ORGANIZATION

TSCA ASSISTANCE OFFICE

- Advises and assists industry, environmental groups, trade associations, public interest groups, states, regions, and other counties on OTS plicy and regulatory prositions relating to TSCA.
- Provides technical assistance to the chemical industry including the small business community by conducting periodic surveys of industyr activities, reporting on EPA actions which may impede or enhance technological innovation and recommending alternative approaches to achieving control of chemical risks.
- Assists Regional Offices in responding to external inquiries to ensure policy consistency.

OFFICE OF PROGRAM MANAGEMENT AND EVALUATION

- Staff office to the Office Director responsible for budgeting, program planning, resource managment, adminisrative operations, and program evaluation.
- Coordinates planning activities necessary to develop recommendations on OTS programs, including the identification of alternative program goals, priorities, objectives and plans.
- Provides input to the Agency's Management Accountability and Reporting System, and develops and implements OTS-wide systems or processes necessary to provide program evaluation.

CHEMICAL CONTROL DIVISION

- Selects and implements appropriate regulatory and non-regulatory controls measures for new chemicals or new uses of such chemicals found to present or potentially present unreasonable risks to human health and/or the environment.
- Responsible for oversight and management of the regulatory evaluation and decision-making processes for new chemicals subject ot premanufacturing notice requirements under section 5.

- Evaluates alternative remedial control measures under TSCA and makes recommendations concerning the existance of unreasonable risk, appropriate regulatory control measures and the priority for action in implementing such control measures.

- Develops generic and chemical-specific rules for new chemicals under section 5 and for new and existing chemicals under section 6 and 7 of TSCA; holds public hearings on such rules as required, and manages any necessary post-promulgation programs such as review of exemption application.

EXISTING CHEMICAL ASSESSMENT DIVISION

- Provides program management for TSCA testing and existing chemicals program. Identifies and manages the evaluation of, and implements non-regulatory remeidal control actions for risks posed by existing chemicals to human health and the environment.

- Identifies specific sources of exposure and potential effects on human health or the environment for whcih testing or control regulations may be warranted and evaluates the types of hazards and degrees of risk reflected in the data and petitions submitted to the Agency under TSCA sections 4, 8, and 21.

- Develops and implements recordkeeping and reporting rules under section 8 of TSCA, to obtain industry data needed to identify and evaluate possible unreasonable risks posed by commercial chemicals.

- Develops and implements procedures for systematically screening available information on existing chemicals and uses of chemicals to identify priority chemicals or categories of chemicals for further evaluation.

- Develops and implements procedures for the selection of specific chemicals or categories for testing under section 4 to include conducting or coordinating the review of relevant data on candidate substances, negotiating industry testing without rulemaking, preparing test rules and conducting public hearings, responding to priority disignations of the TSCA Interagency Testing Committee (ITC), and evaluating requests for exemptions from testing.

- Manages all activities under sections 12 and 13 relating to exports and imports.

HEALTH AND ENVIRONMENTAL REVIEW DIVISION

- Responsible for initial review and detailed assessment of harmful effects of new chemicals on human health and on the environment under TSCA section 5.
- Develops and updates testing guidelines in support of section 4 implementation; reviews, validates, and evaluates test data submitted by industry and other available information relevant to harmful effects of chemicals on human health and the environment; performs scientific assessments of toxicity and other chemical hazards to human health and the environment.
- Provides technical support to the Existing Chemical Assessment Division in implementing TSCA testing and existing chemicals programs and to the Chemical Control Division in rule development for existing chemicals under section 6.
- Identifies and develops new methods and techniques for laboratory testing and evaluation of chemical hazards to human health and the environment through intramural efforrts, extramural studies, and collaboration with the Office of Research and Development and acadeum and international organizations.

EXPOSURE EVALUATION DIVISION

- Responsible for the integrated assessment of human and environmental exposure to substances in support of OTS risk assessment activities.
- Provides standards, guidance, and rule development support to the Chemical Control Division and the Existing Chemical Assessment Division for chemical, physical, and persistence properties testing, analytic methods, field sampling, and other exposue-related data and studies, under section 4, 5, and 6 of TSCA.

- Reviews, evaluates, and validates data submitted by industry and other available information relevant to chemical exposure to humans and the environment, and evaluates human epidemioligcal data and develops guidelines for epidemiological studies.
- Performs scientific assessments of human and environmental exposure to chemical substances.
- Identifies and develops new methods and techniques for laboratory testing, field study, and integrated evaluation of human and environmental exposure.
- Responsible for developing and implementing regulations or polychlorinated biphenyls under section 6(e) of TSCA.

ECONOMICS AND TECHNOLOGY DIVISION

- Responsible for economic, industrial chemistry, and engineering analyses in support of the OTS program activities including rulemaking under section 4, 5, 6, 7, and 8.
- Provides technological input into major risks assessments conducted by OTS.

INFORMATION MANAGEMENT DIVISION

- Responsible for all information and security services in support of TSCA and is the focal point of toxic chemical information in EPA Headquarters.
- Maintains the TSCA chemical inventory and provides search support for all OTS programs.
- Operates the chemical information library which serves as the primary chemical collection for the entire Agency, interacts with the international chemcial information community to exchange data.
- Serves as focal point for receipt and control of all documents received as a result of TSCA rulemaking activity, including the security of these documents.

REGULATORY DEVELOPMENT

REGULATORY PROCESS

For a discussion of the regulatory development process within EPA, see page 233 of this publication.

EXISTING REGULATIONS

Toxic Substances Control Act	40 CFR 700-762

STATUTORY AUTHORITY

The Toxic Substances Control Act
Public Law 94-469 15 U.S.C. § 2601

In 1971, the President's Council on Environmental Quality developed a legislative proposal for coping with the increasing problems of toxic substances. Over the next 5 years, Congress held many hearings, debated and amended the provisions in committee, failed to resolve the differences between the House and Senate bills in the 92nd and 93rd Congresses, and finally passed the present legislation in the fall of 1976. The law grants the U.S. Environmental Protection Agency (EPA) significant new authority to anticipate and address chemical risks.

The Toxic Substances Control Act authorizes EPA to obtain information from industry on the production, use, health effects, and other matters concerning chemical substances and mixtures. If warranted after considering the costs, risks, and benefits of a substance, EPA may regulate its manufacture, processing, distribution in commerce, use, and disposal. Pesticides, tobacco, nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics are exempted from the Act; these products are currently handled under other laws.

Key Sections of Act--Toxics Focus

Section 4--Testing of Chemical Substances and Mixtures

sec. 4(a)	The Administrator shall require by rule the testing of any chemical substance or mixture whose manufacture, distribution, processing, use, or disposal is suspected of presenting an unreasonable risk of injury to health or environment, and about which insufficient data exist to adjudge that risk.
sec. 4(b)	States the requirements for and effects for which testing rules can be developed under subsection 4(a).
sec. 4(c)	Provides for exemptions to the testing rules developed under subsection 4(a).
sec. 4(e)	Provides for the establishment, by committee, of a priority list of chemical substances or mixtures (not to exceed 50) for consideration in the promulgation of rules under subsection 4(a). (Note: This function is performed by the TSCA Interagency Testing Committee [ITC] which was formed in February 1977 and includes representatives from eight Federal agencies.)
sec. 4(f)	Upon receipt of any test data submitted under this Act, or any other available information which indicates that a chemical substance or mixture presents or will present a significiant risk of serious or widespread harm to humans from cancer, gene mutations, or birth defects, the Administrator shall initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk.
sec. 4(g)	A manufacturer or processor may petition for test standards to be set by the Administrator.

Section 5--Manufacturing and Processing Notices (Premanufacturing Notification)

sec. 5(a)	Section 5 requires a manufacturer or processor to notify EPA 90 days before producing either a new chemical substance, i.e., not on the TSCA Inventory of existing chemicals, or an existing chemical intended to be used in a "significantly" new way.

sec. 5(b)	Describes the instances in which a person subject to the notification requirement under subsection 5(a) must submit test data to the Administrator before the manufacture or processing of the substance can begin.
sec. 5(c)	Allows the Administrator, for good cause, to extend the notice review period prescribed by subsections 5(a) and 5(b) for a period not to exceed, in the aggregate, 90 days.
sec. 5(d)	Requires the Administrator to publish in the *Federal Register* all notices received under subsection 5(a) together with data describing health and environmental effects.
sec. 5(e)	Sets out the procedures under which the Administrator can prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a new substance, or significant new use of an existing substance when there is insufficient information to evaluate the health and environmental effects of the substance.
sec. 5(f)	Requires the Administrator to take immediate action to prohibit or limit human or environmental exposure to a new chemical substance, or significant new use of an existing chemical substance, if he finds a reasonable basis to conclude that the substance poses an unreasonable risk.
sec. 5(g)	If the Administrator does not prohibit or limit the manufacturing, processing, etc., of certain new chemicals or new uses of existing chemicals (substances that are listed under subsection 5(b)), then the Administrator must publish his reasons for not initiating the action.
sec. 5(h)	Provides for exemptions to subsections 5(a) and 5(b).

Section 6--Regulation of Hazardous Chemical Substances and Mixtures

sec. 6(a)	The Administrator may prohibit or limit the manufacture, processing, distribution, use, or disposal of a chemical substance or mixture that presents an unreasonable risk of injury to health or the environment.
sec. 6(b)	Allows the Administrator to require the revision of inadequate quality control procedures utilized in the manufacture or processing of chemical substances or mixtures.
sec. 6(c)	Details the procedures for promulgating rules under subsection 6(a).
sec. 6(d)	Allows the Administrator to make a proposed rule immediately effective upon its publication in the *Federal Register*.
sec. 6(e)	Requires the Administrator to prescribe regulations for the labeling and disposal of polychlorinated biphenyls (PCBs). Bans the manufacture, processing, distribution, and use of PCBs in other than a totally enclosed manner by July 1979.

Section 7 --Imminent Hazards

sec. 7(a)	Authorizes the Administrator to bring suit in a U.S. district court for seizure, relief, or both, of any imminently hazardous substance or mixture or article containing it.
sec. 7(b)	The district courts will have jurisdiction to grant temporary or permanent relief for actions brought under subsection 7(a).

sec. 7(d)	Concurrent with or as soon as possible after the filing of an action under subsection 7(a) and, where appropriate, the Administrator shall initiate rulemaking under subsection 6(a).
sec. 7(f)	Defines an imminently hazardous chemical substance or mixture as that which presents an unreasonable risk of serious or widespread injury to health or the environment that is likely to occur before a section 6 action can protect against the risk.

Section 8--Reporting and Retention of Information

sec. 8(a)	Allows the Administrator to promulgate rules for industry (excludes small manufacturers and processors) reporting and retention of information on the manufacture, processing, use, and disposal of chemical substances, byproducts produced, and estimates of the number of people exposed in the workplace.
sec. 8(b)	Requires the publication of an inventory of chemical substances manufactured or processed in the United States.
sec. 8(c)	Requires manufacturers, processors, and distributors to keep records of and submit information on allegations of significant adverse reactions to health and the environment caused by chemicals.
sec. 8(d)	Requires manufacturers, processors, and distributors to submit, upon request, health and safety studies to EPA.
sec. 8(e)	Requires manufacturers, processors, and distributors to immediately notify the Administrator if they have information that reasonably supports the conclusion that a substance or mixture poses a substantial risk to health or the environment.

Section 9--Relationship to Other Federal Laws

sec. 9(a)	Establishes the relationship between the Act and Federal laws not administered by the Administrator.
sec. 9(a)(2)	Authorizes the publication of a report if the Administrator determines that risk may be prevented or significantly reduced by another law.
sec. 9(b)	Establishes the relationship between this Act and other laws administered in whole or in part by the Adminstrator.
sec. 9(c)	Requires that the Administrator consult and coordinate with other Federal agencies to avoid duplication and overlap.

Section 10--Research, Development, Collection, Dissemination, and Utilization of Data

sec. 10(a)	Requires the Administrator to conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act.
sec. 10(b)	Authorizes the establishment of an interagency committee whose primary responsibility shall be to design an efficient system for the collection, dissemination, and use of data submitted to the Administrator under this Act.

Section 12--Exports

sec. 12(a)	Chemical substances or mixtures manufactured or processed solely for export from the United States are exempt from the Act (except for the reporting requirements under section 8) if proper labeling shows they are intended for export use only.
sec. 12(b)	Requires exporters to notify EPA when exporting chemicals for which certain section 4, 5, 6 or 7 actions have been taken. The Agency must in turn notify the country of import of the EPA regulatory action and of the availability of test data.

Section 13--Imports

sec. 13(a)	Authorizes the Secretary of the Treasury to refuse entry of any chemical substance, mixture, or article containing same if it fails to comply with any rule promulgated under this Act, or, if it is in violation of section 5 or 6, a rule or order under section 5 or 6, or an order or civil action brought under section 5 or 7.

Section 14--Disclosure of Data

sec. 14(a)	Any information obtained under TSCA which qualifies as a trade secret or as commercial or financial information must be kept confidential by EPA. An exception may be made where necessary to protect health or the environment.
sec. 14(b)	An exception to confidentiality requirements may also be made for studies which are submitted concerning health and safety effects of certain chemicals.
sec. 14(c)	Any person who submits information to EPA under TSCA may claim that it should be given confidential treatment, and is entitled to receive advance notice if EPA decides not to honor the claim.
sec. 14(d)	Federal employees who knowingly disclose confidential information to persons who are not authorized to receive it are guilty of a misdemeanor and may be subject to a $5,000 fine and/or imprisonment for 1 year.
sec. 14(e)	All information obtained under TSCA must be made available to committees of Congress, regardless of any claim of confidentiality.

Section 21--Citizen's Petitions

sec. 21(a)	States that any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under subsection 5(e) or 6(b)(2).
sec. 21(b)	Details the procedures to be followed.

Regulatory Options Available Under Statute

- EPA may prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical. Such action can range from a labeling requirement to a complete ban.

REGULATORY DEVELOPMENT

REGULATORY PROCESS

For a discussion of the regulatory development process within EPA, see page 233 of this publication.

EXISTING REGULATIONS

Toxic Substances Control Act	40 CFR 710-762

TOXICS-RELATED ACTIVITIES

Within the Office of Toxic Substances, toxics-related activites center on implementing the major provisions of TSCA. Specifically, these include those activities dealing with information gathering and dissemination, testing, premanufacture notification, and chemical control. Brief summraries of these activities are included here. These summaries are intended to familiarize the public with the provisions of the law, not to constitute an authoritative legal statement of it. More detailed information can be obtained from the TSCA Report to Congress for Fiscal Year 1982 (dated January 1983), which is available from the TSCA Assistance Office (in Washington, D.C., 554-1404; or, tollfree 800-424-9065).

Information Gathering and Dissemination

Chemical Substances Inventory

On June 1, 1979, the Agency published the initial Chemical Substances Inventory (under section 8(b) of TSCA) based on information reported to EPA by chemical manufacturers, importers, and processors. The inventory--to which new chemicals are added when they go into production--shows now that nearly 58,000 commercial chemical substances are, or have been, manufactured or imported into the United States since January 1, 1975.

It is important to note that the chemical inventory is not a ist of toxic or hazardous chemicals. Rather, it lists existing chemicals by their specific chemical name (e.g., acetonitrile, bromobenzene, chlormethane, etc.), giving for the first time an overall picture of the chemicals used for commercial purposes in the United States. In addition to being unprecedented, this list is of major importance because chemicals nt on the inventory must be reviewed by EPA under the premanufacture notificationprogram before they are allowed into U.S. commerce.

Section 8 - Reporting and Retention of Information
(Recordkeeping and Reporting)

In addition to compiling the inventory, EPA has used its TSCA reporting authority to obtain production, use, release, and exposure data on a number of chemicals--including asbestos and chemicals recommended by the Interagency Testing Committee for test rule consideration.

TSCA, under section 8(c), also requires any person who manufactures, processes, or distributes in commerce any chemical substance or mixture to keep records of significant adverse reactions to health or the environment that allegedly were caused by the chemical under section 8(d). Records concerning health effects on employees must be kept for 30 years; other records must be retained for 5 years.

The Agency may require the submission of health and safety studies which are known or available to those who manufacture, process, or distribute specified chemicals in commerce under section 8(d).

In addition, under section 8(e), if the chemical industry has information which indicates that a chemical presents a substantial risk of injury to health or the environment, EPA must be notified.

Research, Monitoring and Data Systems

In addition to establishing a data system within the EPA for information submitted under TSCA, the Agency, under the provisions of section 10(b), is responsible for designing and establishing a system for toxicological and other scientific data accessible to all Federal agencies.

EPA has developed the Chemicals-in-Commerce Information System (CICIS) to store and retrieve TSCA data. This system contains TSCA confidential business information and state-of-the-art computer security techniques. The computerized TSCA Inventory became operational in late 1979, and several information services have been derived from it, including subsystems for Freedom of Information Act requests, inventory profiles for EPA Regional Offices, support for the TSCA premanufacture review provess, and health and safety study submissions.

The Interagency Toxic Substances Data Committee (ITSDC), formed in February 1978 by EPA and the Council on Environmental Quality, is continuing its work to construct a comprehensive Chemical Substances Information Network (CSIN).

CSIN enables toxic substances information users to have access to a number of independent and autonomous data banks in the public and private sectors. Users can make use of one computer to manage the logging-in, accessing, and processing of their queries for relevant records in and among many data and information systems--one simple access point to a "library of systems."

III. TESTING OF CHEMICALS

TSCA gives EPA authority to require manufacturers or processors of certain existing chemicals (i.e., those already being distributed in commerce) to test their health and environmental effects. EPA exercises this authority only when it can make certain statutory findings about the substance involved and when industry fails to develop the needed data on its onw. These required findings are: (1) that there are insufficient data already available with which to perform a reasonable risk assessment; (2) that testing is necessary to provide such data; (3) that a chemical may present an unreasonable risk of injury to human health or the environment; or (4) that the chemical is produced to substantial quantities resulting in significant human exposure or environmental release.

Testing requirements are imposed only after a rulemaking proceeding which includes opportunities for both public comments negotiated rules and an oral presentation at a hearing.

An Interagency Testing Committee of government experts on chemical substances advises EPA on those that should be tested; however, actions are not limited to those recommended by the Committee. The eight Committee members represent the Departments of Labor, Commerce, Health and Human Services (including the National Cancer Institute, the National Institute for Occupational Safety and Health, and the National Institute of Environmental Health Sciences), the National Science Foundataion, the Council on Environmental Quality, and EPA. The Committee cannot designate more that 50 priority chemicals for testing at any given time. Within 12 months of designation, EPA must either initiate a rulemaking proceeding to impose testing requirements for those designated chemicals or publish in the Federal Register the resaons for not requiring testing.

PREMANUFACTURE NOTIFICATION

(PREMANUFACTURE AND SIGNIFICANT NEW USE NOTIFICATIONS)

The authors of TSCA recognized that health and environmental considerations are more easily addressed before rather than after a chemical is produced and introduced into commerce. Thus, under section 5 of TSCA, manufacturers or importers of new chemicals must give EPA a 90-day advance notification of their intent to manufacture or import a new chemical. Any chemical which is not listed on the inventory of existing chemicals (discussed previously), published by the Agency, is considered "new" for purposes of this premanufacture notice requirement.

In addition, EPA may designate a use of a chemical as a significant new use, based on consideration of several factors, including the anticipated extend and type of exposure to human beings or the environment. Anyone who intends to manufacture, import, or process a chemical for such a significant new (even if the chemical is on the inventory/or went through premanufacture notification review) must notify EPA 90 days before manufacturing, importing or processing the chemical for that use.

The 90-day review period for new chemicals and significant new uses can be extended by EPA for an additional 90 days for a good cause. Notices submitted for new chemicals, or significant new uses of chemicals, are to include: the identity of the chemical, its molecular structure, proposed categories of use, an estimate of the amount to be manufactured, imported or processed, the by-products resulting from the manufacture, processing, use, and disposal of the chemical, estimates of exposure and any test data related to the health and environmental effects of the chemical. In addition, if a rule requiring testing of the chemical or its chemical class has been issued, the notice must include test data developed from that testing along with the other information.

Chemicals produced in small quantities solely for experimental or research and development purposes are automatically exempt from the premanufacture and significant new use notification requirements. In addition, any person may apply for an exemption for chemicals used solely for test marketing pruposes or those determined by EPA not to present an unreasonable risk of injury to human health or the environment.

If EPA determines that insufficient information is in a notification to evaluate potential risk, the Agency may order that the manufacture or importation of the chemical be prohibited until adequate data are developed. The company is under no time limit to submit the information, but until it does, EPA's ban remains in effect. After reviewing a premanufacture notification containing sufficient data, if EPA determines that the new chemical presents or will present an unreasonable risk of injury to health or the environment, the Agency can, during the review period, prohibit the manufacturing, processing, or distribution in commerce of that chemical.

CHEMICAL CONTROL

REGULATION OF HAZARDOUS CHEMICALS

Under section 6 of TSCA, EPA has the authority to prohibit or limit the manufacture, import, processing, distribution in commerce, use, or disposal* of a chemical when these activities are found to pose an unreasonable risk of injury to human health or the environment. A number of possible control options are available, ranging from total prohibition to labeling.

A manufacturer or processor may be required to make and keep records of the processes used in manufacturing a chemical and to conduct tests to assure compliance with any regulatory requirements. Further, the Agency may require a manuacturer or processor to give notice of any unreasonable risk of injury presented by his chemical to those who purchase or may be exposed to that substance. A manufacturer or processor may also be required to recall a substance which presents an unreasonable risk.

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* Distinction Between Disposal Authority of TSCA & RCRA: TSCA has the authority to regulate the disposal stage of a chemical's life cycle on a chemical-by-chemical basis, that is once a particular chemical s determined to be an unreasonable risk to human health and the environment (e.g., PCBs). The Resource Conservation and Recovery Act (RCRA) has the authority to establish regulations and programs to ensure safe waste treatment and disposal of any number of chemicals.

In proposing regulatory actions, EPA must provide an opportunity for comments by all interested parties.

A rule limiting, but not banning, a chemical may be made immediately effective when initially proposed in the *Federal Register* if the Agency determines that the chemical *is likely* to present an unreasonable risk of serious or widespread injury to health or the environment before normal rulemaking procedures could be completed. In the case of a rule prohibiting the manufactuer of the chemical, EPA must first obtain a court injunction before the rule can be made immediately effective.

For those chemicals that present an imminent and unreasonable risk of serious or widespread injury to health or the environment, EPA may ask a court to require whatever action may be necessary to protect against such risk.

Polychlorinated Biphenyls (PCBs)

In TSCA, Congress singled out Polychlorinated biphenyls (PCBs) for both immediate regulation and phased withdrawal from the market. EPA may authorize certain uses of PCBs and may exempt, pursuant to certain TSCA criteria, specific activities involving the manufacturing, processing, or distribution in commerce of PCBs.

Exports and Imports

If a person intends to export a chemical which is subject to certain testing or regulatory control requirements under TSCA, he must notify EPA. The AGency is responsible for notifying the importing country's government of the export and of EPA's regulatory action or the availability of information.

With respect to imports, no chemical substance, mixture, or article containing a chemical substance or mixture will be alowed into the customs territory of the United States if it fails to comply with any TSCA rule or otherwise violates TSCA.

Chemicals produced solely for export are generally not subject to TSCA. However, in the case of a chemical produced for export that presents an unreasonable risk of injury to health or the environment in the United States, EPA may regulate the chemical. Testing may also be required for any exported chemical if it is necessary to determine whether there is such a risk to the United States.

OFFICE OF PESTICIDE PROGRAMS

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-557-7090

Organization....................Page 238
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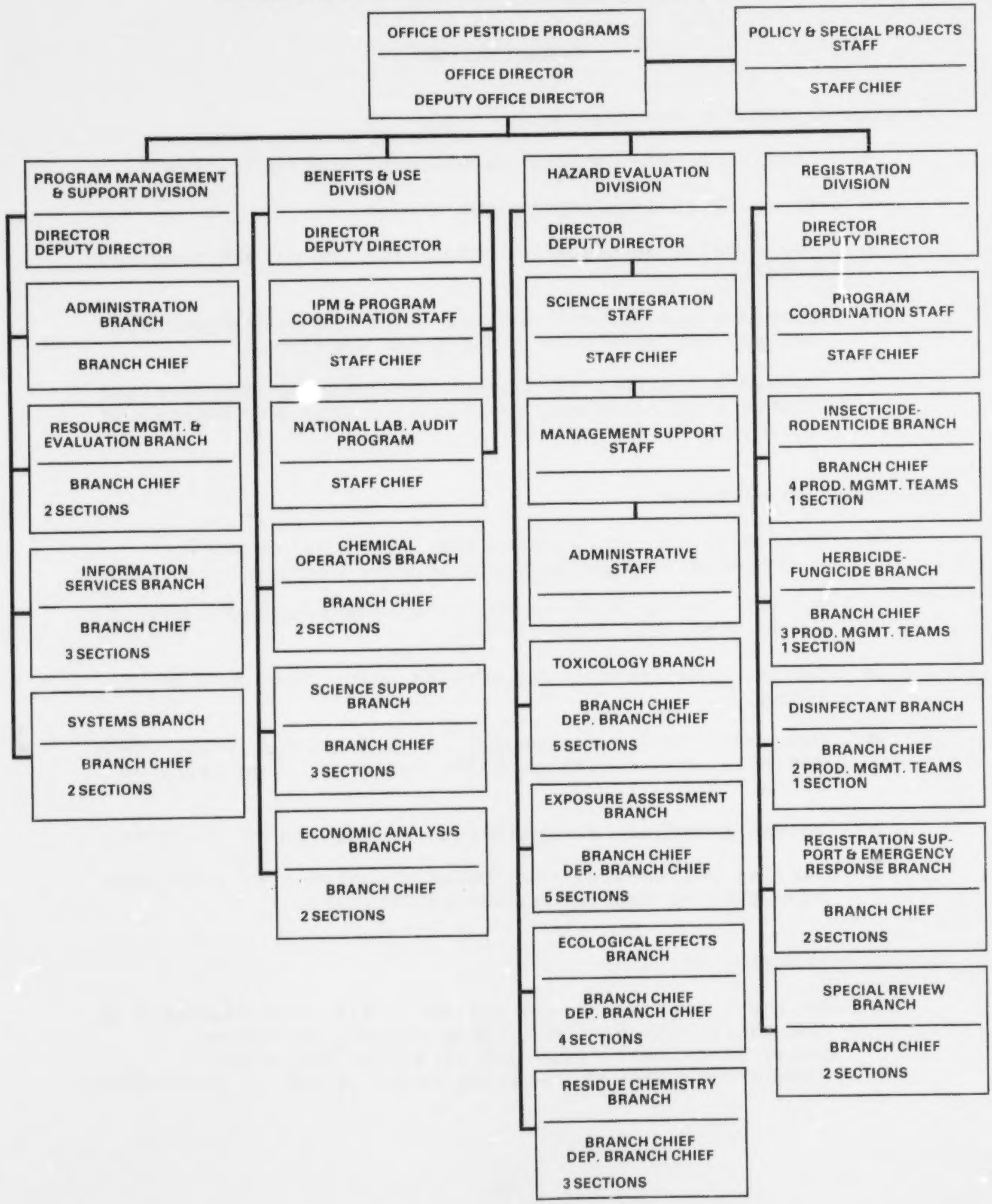
Regulatory Development...........Page 246
Toxic-Related Activities.........Page 247

The Office of Pesticide Programs is responsible for implementing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). As such, the Office coordinates all Agency programs concerning pesticide management and regulation, including the establishment of tolerance levels for pesticide residues which occur in or on food; the registration and reregistration of pesticides; the monitoring of pesticide levels in food, humans, and nontarget fish and wildlife; and the preparation of guidelines and standards for products in the development of more effective pesticide control programs. In addition, the Office provides policy direction to technical and manpower training activities in the pesticide area; develops research needs and monitoring requirements for the pesticide program; reviews impact statements dealing with pesticides; and carries out assigned international activities.

OFFICE OF PESTICIDE PROGRAMS


OFFICE OF PESTICIDE PROGRAMS
OFFICE DIRECTOR
DEPUTY OFFICE DIRECTOR
POLICY & SPECIAL PROJECTS STAFF
STAFF CHIEF
PROGRAM MANAGEMENT & SUPPORT DIVISION
DIRECTOR
DEPUTY DIRECTOR
ADMINISTRATION BRANCH
BRANCH CHIEF
RESOURCE MGMT. & EVALUATION BRANCH
BRANCH CHIEF
2 SECTIONS
INFORMATION SERVICES BRANCH
BRANCH CHIEF
3 SECTIONS
SYSTEMS BRANCH
BRANCH CHIEF
2 SECTIONS
BENEFITS & USE DIVISION
DIRECTOR
DEPUTY DIRECTOR
IPM & PROGRAM COORDINATION STAFF
STAFF CHIEF
NATIONAL LAB. AUDIT PROGRAM
STAFF CHIEF
CHEMICAL OPERATIONS BRANCH
BRANCH CHIEF
2 SECTIONS
SCIENCE SUPPORT BRANCH
BRANCH CHIEF
3 SECTIONS
ECONOMIC ANALYSIS BRANCH
BRANCH CHIEF
2 SECTIONS
HAZARD EVALUATION DIVISION
DIRECTOR
DEPUTY DIRECTOR
SCIENCE INTEGRATION STAFF
STAFF CHIEF
MANAGEMENT SUPPORT STAFF
ADMINISTRATIVE STAFF
TOXICOLOGY BRANCH
BRANCH CHIEF
DEP. BRANCH CHIEF
5 SECTIONS
EXPOSURE ASSESSMENT BRANCH
BRANCH CHIEF
DEP. BRANCH CHIEF
5 SECTIONS
ECOLOGICAL EFFECTS BRANCH
BRANCH CHIEF
DEP. BRANCH CHIEF
4 SECTIONS
RESIDUE CHEMISTRY BRANCH
BRANCH CHIEF
DEP. BRANCH CHIEF
3 SECTIONS
REGISTRATION DIVISION
DIRECTOR
DEPUTY DIRECTOR
PROGRAM COORDINATION STAFF
STAFF CHIEF
INSECTICIDE-RODENTICIDE BRANCH
BRANCH CHIEF
4 PROD. MGMT. TEAMS
1 SECTION
HERBICIDE-FUNGICIDE BRANCH
BRANCH CHIEF
3 PROD. MGMT. TEAMS
1 SECTION
DISINFECTANT BRANCH
BRANCH CHIEF
2 PROD. MGMT. TEAMS
1 SECTION
REGISTRATION SUPPORT & EMERGENCY RESPONSE BRANCH
BRANCH CHIEF
2 SECTIONS
SPECIAL REVIEW BRANCH
BRANCH CHIEF
2 SECTIONS

ORGANIZATION

PROGRAM MANAGEMENT AND SUPPORT DIVISION

- Assists in OPP program development and evaluation.
- Prepares various OPP budget proposals.
- Coordinates development and evaluation of OPP research needs.
- Provides and manages central files and correspondence control and technical information services.
- Provides centralized support services for computerized statistical analyses, systems analyses, and design and operation of ADP systems.

REGISTRATION DIVISION

- Evaluates and coordinates the registration and reregistrations of pesticides under Section 3 of FIFRA.
- Establishes tolerances for pesticide residues under the Food, Drug, and Cosmetic Act.
- Issues experimental use permits under section 5 of FIFRA.
- Oversees State experimental use and special local needs registration activities under sections 5 and 24(c) of FIFRA.
- Issues emergency exemptions under section 18 of FIFRA.
- Carries out special risk/benefit analyses of chemicals suspected of causing unreasonable risks.

HAZARD EVALUATION DIVISION

- Reviews, evaluates, and validates all data submitted on the toxicological and adverse effects on humans, domestic animals, fish and wildlife, and other biological species resulting from the use of pesticides.

- Performs risk assessments on proposed and existing pesticide uses.
- Provides scientific expertise on adverse effects of pesticides to other Agency programs and other Federal Agencies.

BENEFITS AND USE DIVISION

- Retrieves, validates, and interprets scientific and technical data relative to benefits derived from the use of pesticides.
- Conducts economic analyses on the impacts of cancellations/suspensions and on special or emergency pesticide use applications.
- Develops scientific data on the magnitude and effects of exposure to pesticides on the population by determining residues and metabolites through analytical methods development.
- Provides data on the amount of environmental exposure from pesticides of particular regulatory concern to the agency.
- Maintains pesticide laboratory capability to detect pesticide traces in environmental media and to characterize components of complex chemical formulations.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone	Mail Stop
Office of Pesticide Program	703-557-7090	TS-766
Policy and Special Projects Office (general program information)	703-557-7102	TS-766
Program Management and Support Division	703-557-2440	TS-757
Registration Division	703-557-7760	TS-767

Hazard Evaluation Division	703-557-7351	TS-769
Benefits and Use Division	703-557-0500	TS-768

STATUTORY AUTHORITIES

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Public Law 92-516 7 U.S.C. § 136

Agricultural chemicals have been regulated by the Federal Government since the turn of the century. The present law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), was passed in 1947 and significantly amended several times since then, most recently in 1978. It was administered by the Department of Agriculture until 1970 when jurisdiction was transferred to the Environmental Protection Agency. The purpose of the Act is to control the use of pesticides to safeguard the health of the public and to prevent adverse effects on the environment.

Key Sections of Act--Toxics Focus

sec. 2	Defines terms related to pesticides production and use.
sec. 3	Requires registration, reregistration, and classification of pesticides; authorizes conditional registration pending full data development in certain circumstances.
sec. 3(g)	Requires that pesticides leaving postharvest residues on food or field crops be given priority in the reregistration process.
sec. 4	Authorizes EPA to prescribe standards for the certification of pesticide applicators and use of restricted use pesticides.
sec. 4(c)	Encourages distribution of instructional materials on integrated pest management (IPM).
sec. 5	Provides for issuance of experimental use permits for new pesticides so that data required for registration may be gathered.

sec. 6(a)	Requires cancellation of registration after 5 years unless a request for continuance is submitted and approved.
sec. 6(b)	Authorizes EPA to cancel pesticides that cause unreasonable adverse effects on the environment.
sec. 6(c)	Authorizes EPA to suspend the registration of a pesticide immediately to prevent an "imminent hazard."
sec. 7	Requires registration of pesticide production facilities.
sec. 8(a)	Authorizes EPA to require that producers maintain books and records.
sec. 8(b)	Authorizes EPA to conduct in-plant inspections of books and records.
sec. 9	Authorizes EPA to make in-lant inspections and obtain samples of pesticides, devices, packages, and labels for purposes of enforcement.
sec. 9(b)	Authorizes EPA to obtain and execute warrants.
sec. 9(c)	Requires certification of facts to the Attorney General by EPA for enforcement purposes.
sec. 10	Provides for protection of trade secrets.
sec. 11	Exempts private pesticide applicators from recordkeeping.
sec. 12	Defines unlawful acts.
sec. 13	Authorizes the Adminstrator to issue a "stop sale, use, or removal" order for pesticides or devices which are in violation of any provisions of this Act.
sec. 14	Details the civil and criminal penalties for violation of the provisions of this Act.
sec. 15	Authorizes the Administrator to issue an indemnity payment under certain conditions.
sec. 16(b)	Allows persons to obtain judicial review on EPA actions against pesticides.

sec. 17(a)	Permits export of pesticides if in compliance with various labeling requirements of the Act. Requires a purchaser acknowledgment statement prior to export of an unregistered pesticide.
sec. 17(b)	Requires EPA to furnish notices of registration, cancellation, or suspension to foreign governments.
sec. 17(c)	Details procedures to follow regarding the import of pesticides.
sec. 18	Authorizes emergency exemptions from provisions of the Act to Federal agencies and States to meet pest control emergencies, and requires consultation with affected Governor(s).
sec. 19	Authorizes EPA to establish procedures and regulations for the safe disposal and/or storage of pesticides and pesticide containers and to accept for disposal, upon request of the owner, any cancelled pesticides.
sec. 20	Authorizes research and monitoring activities.
sec. 23	Authorizes cooperative agreements with States and Indian tribes for enforcement and training of certified applicators.
sec. 24	Authorizes State registration of pesticides, consistent with section 3, for use within the State to meet special local needs.
sec. 26	Gives States primary responsibility for enforcement of the Act.
sec. 28	Requires EPA to cooperate with the Department of Agriculture to identify pests and develop controls.

Regulatory Options Available Under Statute

- Require registration of pesticides
- Prescribe standards for certification of applicators
- Classification for general or restricted use
- Cancel registration
- Suspension of registration in imminent hazard circumstances and cancellation upon final determination by the Administrator

- Regulate storage and disposal of pesticides and pesticide containers (see also, Resource Conservation and Recovery Act)
- Seizure of unregistered, etc., pesticides.

The Federal Food, Drug, and Cosmetic Act (FFDCA)*

Public Law 69 21 U.S.C. §§ 301-392

The Federal Food, Drug, and Cosmetic Act was passed in 1938 to replace the earlier Food and Drug Act of 1906. National legislation in this area became necessary as competition between food manufacturers for sales profits led to the debasement and/or the mislabeling of foods and other products. However, weaknesses in the 1906 Act were pointed out when 107 deaths resulted from "Elixir of Sulfanilamide." This incident called attention to the need for premarket testing of new drugs. The 1938 Act addressed these needs and brought cosmetics under FDA regulation as well.

The purposes of the Food, Drug, and Cosmetic Act are to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that medical devices are safe and effective for their intended uses, including drugs used in medicated feeds for animals; that cosmetics are safe and properly labeled; and that packaging and labeling of these products is truthful and informative.

Since 1938, the Act has been amended several times. Among the more prominent amendments have been the Food Additives Amendment of 1958, which prohibits the introduction of new food additives until the manufacturer can prove their safety; the Color Additive Amendments of 1960 which gave FDA authority to control the conditions for safe use of a color additive, including the amount of color used in a product; and the Drug Amendments of 1962, which required, among other things, that all drugs be proven effective as well as safe.

EPA has the authority, under sections 406, 408, and 409 of this Act, to establish tolerance levels for pesticide residues in food. A tolerance is the legal maximum residue of a pesticide chemical allowed to remain in or on a food. Under the FFDCA, if the residue exceeds the tolerance level then the food is "adulterated" and is subject to seizure by the Food and Drug Administration (FDA). The tolerance requirements of the FFDCA are also applicable to imported food, whether or not the pesticide is registered for use in the United States.

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*Note: The Food and Drug Administration (FDA) is responsible for implementing most of the provisions of this statute and for enforcing tolerance levels set by EPA. FDA is covered in another section of this publication.

Key Sections of Act--Toxics Focus

sec. 406	Permits the establishment of tolerances for poisonous or deleterious substances including pesticides which (1) are required in the production of food or (2) otherwise cannot be avoided by good manufacturing practices.
sec. 408	Authorizes the establishment of tolerances for pesticides used in or on food or feed.
sec. 409	Authorizes the establishment of tolerances for pesticides which are food additives. (A pesticide is a food additive when (1) it is carried over from use of a raw agricultural commodity and after processing remains in the processed food at a concentration higher than originally found in the raw agricultural commodity, or (2) it is added to a processed food.)

Regulatory Options Available Under Statute

- Set tolerances/revoke tolerances
- Deem products to be misbranded
- Establish standards or conditions
- Require registration or certification

REGULATORY DEVELOPMENT

REGULATORY PROCESS

For a discussion of the regulatory process within EPA, see page 232 of this publication.

EXISTING REGULATIONS

Federal Insecticide, Fungicide, and Rodenticide Act	40 CFR 160-180

TOXICS-RELATED ACTIVITIES

Registration of Pesticides

Registration or pre-market clearance of pesticides involves a comprehensive review of human and environmental risks and a limited review of benefits data submitted by industry. Risk is often quantified in terms of the number or probability of certain health and environment effects, while benefits are usually expressed in dollar values of such effects as increased crop yields, lower food costs, reduced chance of disease, or the cost savings with respect to the use of alternative control measures.

The Federal Pesticide Act of 1978, which amended FIFRA, authorized a program for EPA to grant conditional registrations. Under this program, EPA is able to process applications of new products which are similar to ones already registered and new uses of old chemicals if sufficient information is available to evaluate the unique hazards posed by new uses. New chemicals are also eligible for conditional registration if EPA determines that the public interest would be served by registration, and if unreasonable risks will not be incurred during the period required to complete and submit additional studies.

Central to the conditional registration program is incremental risk assessment. The amended FIFRA requires the Agency to focus its attention only on the increased risks or incremental risks resulting from the registration of old pesticides and new uses of old pesticides. Specifically, conditional registration of both identical and substantially similar products and uses and new uses is authorized only if the new use or product will not significantly increase the risk of unreasonable adverse effects on the environment.

In Fiscal Year 1982 the registration program continued to give top priority to environmentally safe and innovative compounds and technologies, such as biorational compounds and other alternative means of pest management. During Fiscal Year 1982, the Registration Program received 232 new active ingredients, 11,020 previously registered active ingredients, and 23,309 amendments and supplemental registration applications.

Pesticide Tolerances

Under the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA), the Agency is required to establish tolerance levels and exemptions from the requirements for a tolerance. These tolerance levels protect the public health while giving appropriate consideration to the production of an adequate, wholesome, and economical food supply. Determination of tolerances involves careful review and evaluation of residue chemistry and toxicology safety data to ensure that maximum residue levels likely to be found in food or feed are safe for human consumption. Included in this consideration is the cumulative effect of the respective pesticide and related substances with the same physiological activity.

Registration (Generic) Standards

The Registration Standards System, a new approach to reregistration sanctioned by the 1978 amendments, will streamline the reregistration process. Instead of reregistering each of the approximately 50,000 products on a case-by-case basis, the Agency is developing comprehensive registration standards for each active ingredient common to numerous pesticide products. Out of the 50,000 registered pesticide products, EPA is concentrating its effort on the review of approximately 600 chemicals (active ingredients) representing the major pesticide chemicals produced. The registration standards program is an on-going, long-term project and by the end of fiscal year 1982, 43 standards had been issued.

The development of a registration standard is divided into five phases: (1) Phase I--Data gathering and preparation, (2) Phase II--Scientific review, (3) Phase III--Identification and analysis of regulatory options, (4) Phase IV--Regulatory standard drafting and publication, and (5) Phase V--Integration of comments and preparation of the revised standard.

For every pesticide chemical and its formulations, safety criteria are set, to which registrants must adhere, in order to register and reregister products. An intensive risk/benefit review will be conducted only for those chemicals which meet the "unreasonable adverse effects" criteria. All other chemicals require a risk analysis only. In addition, standards for registration state tolerable levels of exposure for food consumers, field workers, applicators, and other persons and organisms unintentionally exposed to pesticides, and facilitate reassessments of tolerances to minimize pesticide exposure of workers, applicators, and others.

Special Review

The Special Review (formerly known as Rebuttable Presumption Against Registration, RPAR) process is an intensive risk/benefit review of pesticide chemicals suspected of causing unreasonable adverse health or environmental impact. The process involves development of recommendations for a regulatory position with regard to the registration, suspension, cancellation, restriction on uses, or removal of pesticides containing the chemical under review.

The Special Review process begins when a suspected pesticide chemical is referred to the Special Review Branch for consideration. Before this chemical can be accepted as an Special Review candidate, data supporting the statement of risk must be scientifically validated. The first part of the Special Review process focuses on the development of a risk assessment, followed by a publication of the Agency's position on the chemical in the Federal Register. During the comment period, the public, manufacturers, and users are given an opportunity to offer evidence in rebuttal or in support of the presumption against registration.

If the rebuttal comments are unsuccessful, the Agency develops a risk/benefit analysis for each significant use and each regulatory option of the special review. Representing the proposed Agency decision, the second Position Document is published in the Federal Register followed by a second public comment period. The tentative Agency decision and supporting data are reviewed by USDA and the EPA Scientific Advisory Panel (SAP). Their recommendations and appropriate public comments are incorporated into the final regulatory document and forwarded to the Assistant Administrator, Office of Pesticides and Toxic Substances, for approval. After this comprehensive review and sign-off process is completed, EPA publishes the final decision in the Federal Register. The Agency may decide to register or reregister or restrict all or some of the uses of the pesticide. During 1982, the Agency placed increased emphasis on negotiations with Special Review Chemical Registrants to reach environmentally sound decisions more quickly.

In 1982, OPP completed Special Reviews for 15 chemicals. Some of the more important Special Review decisions included the following chemicals: Toxaphene, Benomyl, Paraquat and the EBDC Fungicides. By the end of 1982, the Agency has reached proposed or final decisions on approximately 90% of the original list of suspect chemicals in the mid-1970's. In the future, risk benefit evaluating will be initiated as a result of reviews or new data developed through the registration standards process.

Laboratory Audit Program

The Office of Pesticide Programs established a Laboratory Audit Program because of indications that there were defects in basic studies used to support pesticide registrations. The data validation process is critical to all the basic regulatory programs in OPP, including removal or restriction of hazardous pesticides and development of registration standards.

In cooperation with the Federal Drug Administration and EPA's Office of Enforcement, OPP personnel have been managing systematic audits of independent testing laboratories which generate toxicology data in support of the registration of pesticides. After conducting laboratory audits, OPP audit personnel recommend appropriate regulatory and/or judicial action.

During Fiscal Year 1982, OPP personnel, in collaboration with FDA, conducted 21 on-site data audits involving validation reviews of possibly faulty lab data.

Special Registration of Pesticides

The Special Registration Program was established to respond promptly and effectively to unexpected and temporary health and agricultural exigencies and to support State and local governments in registering pesticides for local or State use. Under the Special Registration Program, OPP issues emergency exemptions under section 18 of the FIFRA, Experimental Use Permits (EUPs) under section 5, and temporary tolerances to establish safe levels of pesticide residues in food and feed from pesticide use for experimental purposes.* OPP also monitors section 24(c) registrations by States, and minor use registrations or minor use/specialty crop petitions for tolerance submitted by public interest user-orinented groups, such as the Inter-Regional Research Project No. 4 (IR-4) based at Rutgers University.

Under the Special Registration Program, emergency exemptions may be granted to State or Federal agencies, authorizing pesticides to be used for purposes not included on registered labeling. Emergency situations which are deemed to justify granting of an emergency exemption must meet the following requirements: (1) A pest outbreak has occurred or is about to occur and no pesticide registered for the particular use, or alternative method of control, is available to eradicate or control the pest, (2) significant economic or health problems will occur without the use of the pesticide, and (3) the time available from discovery or prediction of the pest outbreak is insufficient for a pesticide to be registered for the particular use. In determining whether an emergency condition exists, OPP scientists and product managers carefully evaluate the benefits as well as the human and environmental risks associated with the use of such pesticides.

Because of the extremely broad authority provided under section 18 of FIFRA regarding emergencies, these exemptions may include use of pesticides on crops for which no tolerances have been established (approximately 95 percent fall into this category) and, in rare cases, pesticides which have been cancelled for the proposed use. Granting of emergency exemptions results in reduced annual crop losses amounting to millions of dollars each year. The exemptions have spared growers catastrophic economic losses and have prevented the loss of millions of pounds of valuable food commodities. Emergency exemptions also have been granted for various public health emergencies, such as rabies and plague; quarantine situations, such as Mediterranean Fruit Fly; and for protection of endangered species.

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*Temporary tolerances submitted in support of EUPs allow for continuing pesticide research on agricultural crops used for feed or food.

Experimental Use Permits (EUPs) allow registrants to perform large-scale experimentation needed for the development of data for new pesticides or new uses of currently registered pesticides. Data generated from the issuance of EUPs are used to evaluate the potential hazards to man and the environment from the use of these pesticides. In cases where crops will not be destroyed after the experimental program is ended, a temporary tolerance for a safe residue level on the food or feed commodity must be established by the Agency before the EUP is issued. The Office of Pesticide Programs issues EUPs and establishes temporary tolerances based upon a case-by-case scientific determination of the human and environmental risks and benefits associated with the use of a particular pesticide.

The Special Registration Program also includes approval or disapproval of State registrations of pesticides that are distributed and used only within a particular registering State. In conjunction with the State registration overview authority, OPP monitors the issuance of experimental use permits that are needed to support subsequent State registrations.

OFFICE OF WATER

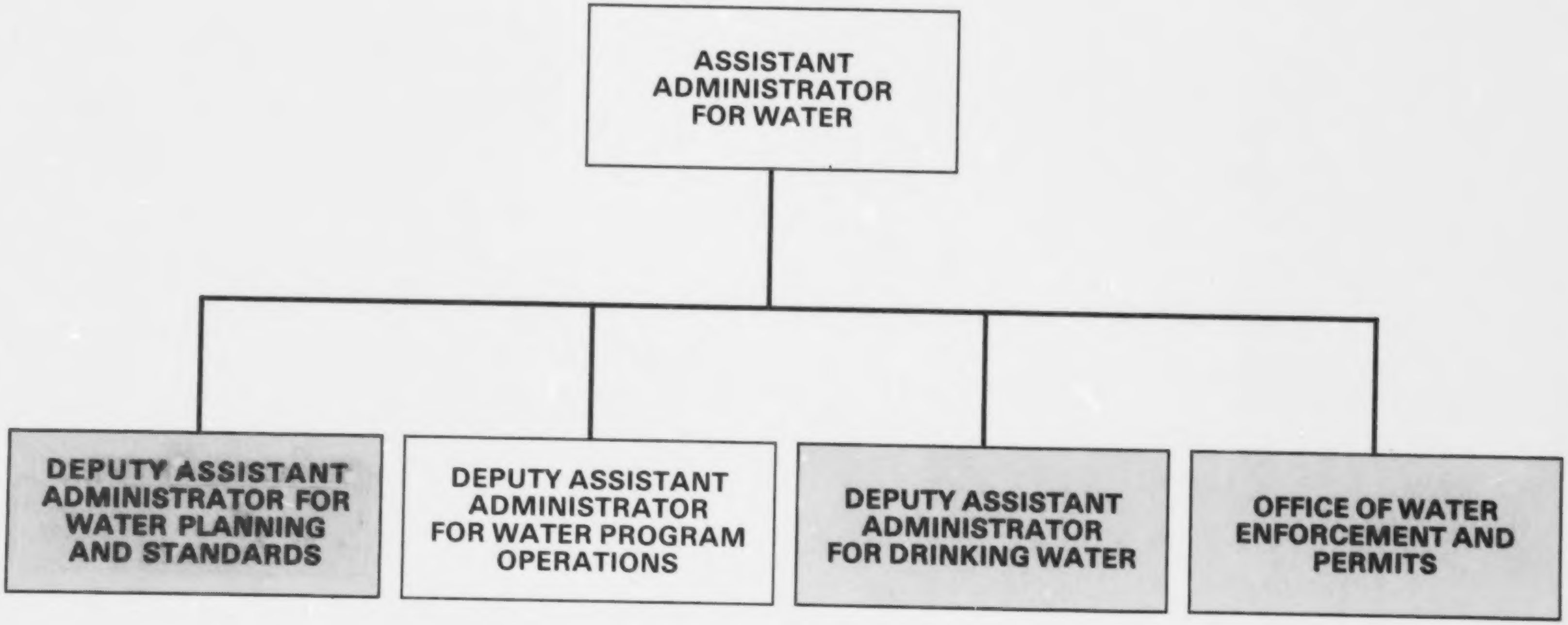
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-5700

This Office is responsible for EPA activities pertaining to the management of water programs. These responsibilities include program policy development and evaluation, standards development, overview, and technical support.

There are four major offices within the Office of Water. Three of those offices are highlighted in this publication. They include the Office of Water Regulations and Standards, which has major responsibilities under the Clean Water Act (as amended 1977); the Office of Drinking Water, which is responsible for Agency activities under the Safe Drinking Water Act (as amended 1977); and the Office of Water Enforcement and Permits, which develops policies for compliance monitoring and enforcement actions and for management of the National Pollutant Discharge Elimination System (NPDES) under the Clean Water Act as amended.

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF WATER
ORGANIZATIONAL CHART*


ASSISTANT ADMINISTRATOR FOR WATER
DEPUTY ASSISTANT ADMINISTRATOR FOR WATER PLANNING AND STANDARDS
DEPUTY ASSISTANT ADMINISTRATOR FOR WATER PROGRAM OPERATIONS
DEPUTY ASSISTANT ADMINISTRATOR FOR DRINKING WATER
OFFICE OF WATER ENFORCEMENT AND PERMITS

*NOTE: A partial organizational chart is shown to highlight (in gray) those components of the Office of Water and Waste Management ordinarily involved in toxic substances activities.

OFFICE OF WATER REGULATIONS AND STANDARDS

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-5400

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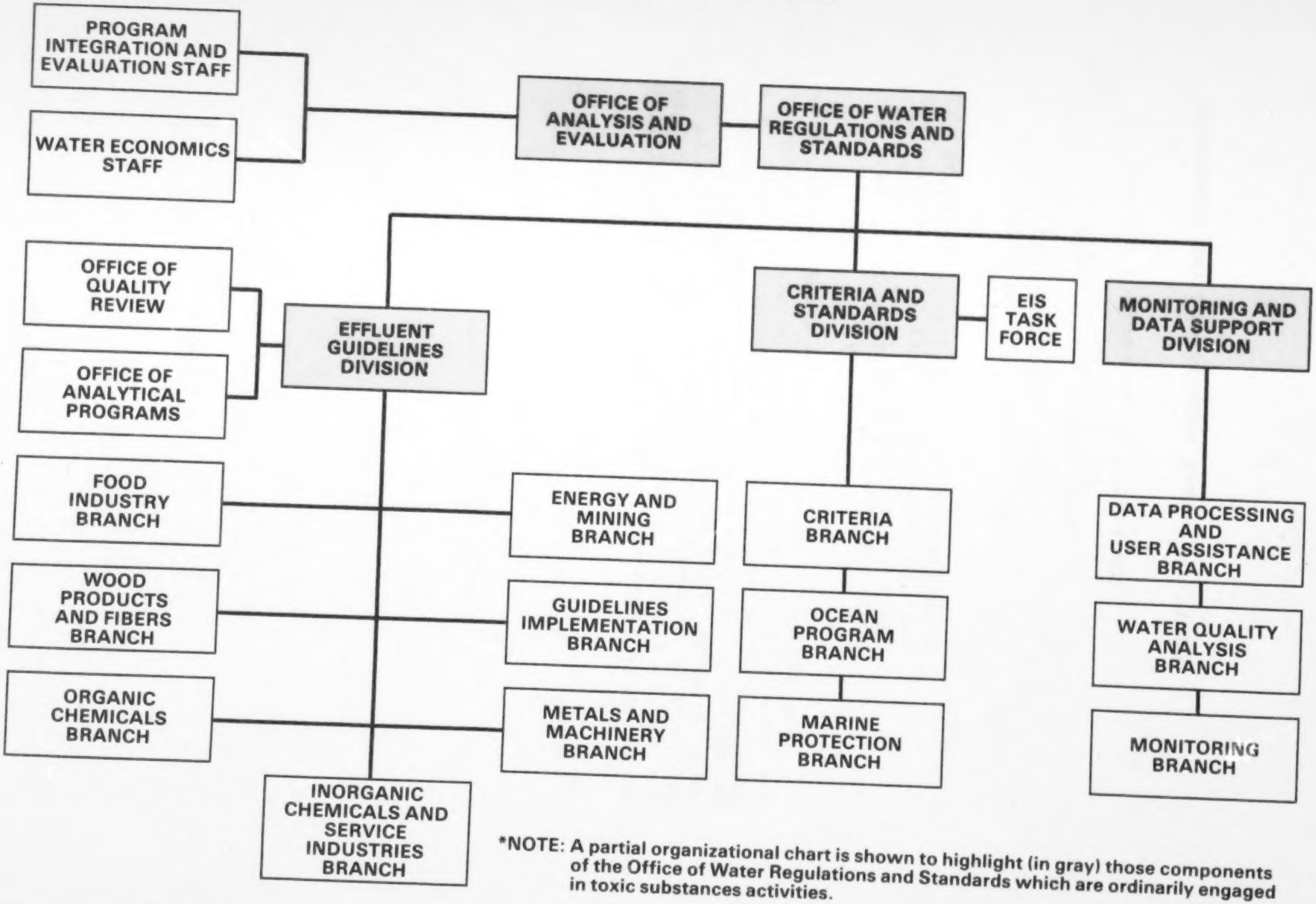
The Office of Water Regulations and Standards is responsible for developing an overall program strategy for the achievement of water pollution abatement and control. As such, it assures the coordination of all national water-related activities within this water program strategy, and monitors national progress toward the achievement of water quality goals. The Office is responsible for the development of effluent standards for industrial sources, water quality monitoring and ocean dumping regulations.

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF WATER
OFFICE OF WATER REGULATIONS AND STANDARDS
ORGANIZATIONAL CHART


PROGRAM INTEGRATION AND EVALUATION STAFF
WATER ECONOMICS STAFF
OFFICE OF ANALYSIS AND EVALUATION
OFFICE OF WATER REGULATIONS AND STANDARDS
OFFICE OF QUALITY REVIEW
OFFICE OF ANALYTICAL PROGRAMS
EFFLUENT GUIDELINES DIVISION
CRITERIA AND STANDARDS DIVISION
EIS TASK FORCE
MONITORING AND DATA SUPPORT DIVISION
FOOD INDUSTRY BRANCH
ENERGY AND MINING BRANCH
WOOD PRODUCTS AND FIBERS BRANCH
GUIDELINES IMPLEMENTATION BRANCH
ORGANIC CHEMICALS BRANCH
METALS AND MACHINERY BRANCH
INORGANIC CHEMICALS AND SERVICE INDUSTRIES BRANCH
CRITERIA BRANCH
OCEAN PROGRAM BRANCH
MARINE PROTECTION BRANCH
DATA PROCESSING AND USER ASSISTANCE BRANCH
WATER QUALITY ANALYSIS BRANCH
MONITORING BRANCH

*NOTE: A partial organizational chart is shown to highlight (in gray) those components of the Office of Water Regulations and Standards which are ordinarily engaged in toxic substances activities.

ORGANIZATION

OFFICE OF ANALYSIS AND EVALUATION

- Develops a national water pollution abatement and prevention plan which sets forth the framework for implementing Agency water-related activities in an integrated, coordinated and timely manner.

- Performs economic analyses and inflationary impact statements to support regulations developed by the Office of Water Regulations and Standards for the abatement and control of point and nonpoint sources of pollution and for monitoring, planning activities and other regulatory programs of the Office of Water Regulations and Standards.

- Provides statistical support and expert review of all regulations developed by the Office of Water Regulations and Standards and those of other offices upon request. Also provides statistical and operations research assistance to the monitoring activity and the water quality standards process.

- Performs in-depth analyses and evaluations on the effectiveness of programs operating within the Office of Water Regulations and Standards.

EFFLUENT GUIDELINES DIVISION

- Develops industrial point source effluent limitations and pretreatment standards for controlling the discharge of toxic, nonconventional and conventional pollutants into the Nation's waterways.

- Provides engineering and analytical technical expertise in defining the most appropriate technologies for pollution control.

- Conducts in-depth technical studies relating to annovative and alternative treatment technologies and recycling and reuse of wastewater to minimize the overall discharge of all toxics into the environment.

- Conducts engineering analyses and data acquisition to evaluate the occurrence and impact of toxic pollutants in the raw waste and treated wastewaters and sludge streams discharged by industry.

- Provides assistance to State and Regional Permit Writers in resolving engineering, economic and scientific problems arising from permitting activities based upon effluent guidelines.

CRITERIA AND STANDARDS DIVISION

- Develops and revises water quality criteria.
- Develops water quality standards, which when adopted by the States, will provide water quality for the protection and propagation of fish, shellfish and wildlife and for recreation in and on the water.
- Assists the States in implementing water quality based standards programs which when used in combination with the technology based approach will provide the most equitable approach to improving the water quality of the Nation's waters.
- Serves as an authoritative source of technical and scientific information on water quality criteria and standards and the effects of water pollutants on health and welfare.
- Develops regulations regulating ocean disposal under the Marine Protection Research and Sanctuaries Act (MPRSA). Designates sites and issues permits for disposal pursuant to MPRSA.

MONITORING AND DATA SUPPORT DIVISON

- Develops water quality monitoring strategies, systems and procedures to identify the biological and chemical measures of environmental quality.
- Develops procedures to assist the States in using water quality data in technical analyses.
- Provides national guidance and technical assistance for State efforts to analyze and report on their water quality and to identify priority problem areas and needed State action to implement required controls.
- Assists States in conducting WLAs and TMDLs and in coordinating local cooperative monitoring programs.

- Obtains, reviews, stores and analyzes ambient chemical, biological, ecological and other data relating to toxic substances.

DIRECTORY FOR TOXICS-RELATED OFFICES/PERSONNEL

DIVISION/OFFICE	Phone*	Mail Stop
Office of Water Regulations and Standards	202-382-5400	WH-551
Office of Analysis and Evaluation	202-382-5389	WH-586
Effluent Guideline Division	202-382-7120	WH-552
Criteria and Standards Division	202-755-0100	WH-585
Monitoring and Data Support Division	202-382-7040	WH-553

*FTS number are the same.

STATUTORY AUTHORITIES

Clean Water Act
Public Law 95-217 33 U.S.C. § 466

The Clean Water Act was passed in 1972 as the Federal Water Pollution Control Act. It represented a major reorientation of Federal efforts to achieve and maintain acceptable levels of water quality. The Act established a national goal of eliminating pollutant discharges into the Nation's waterways by 1985. In 1977, amendments to the Act helped shift attention to the control of toxic pollutants.

The purpose of the Act is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters.

Key Sections of Act--Toxics Focus

sec. 301	Requires application of best available technology economically achievable to prevent discharge of toxic and nonconventional pollutants from point sources.
sec. 302	Authorizes EPA to establish effluent limitations to attain or maintain water quality.
sec. 303	Requires States to issue water quality standards and implementation plans.
sec. 304	Requires EPA to publish: (a) Water quality criteria information. (b) Regulations providing guidelines for effluent limitations. (c) Information on processes which eliminate or reduce the discharge of pollutants. (d) Information on the degree of effluent reduction attainable through the application of secondary treatment. (e) Regulations supplementing the effluent limitations in order to regulate toxic or hazardous pollutants. (f) Information identifying and evaluating nonpoint sources of pollution.

sec. 307	Requires EPA to publish a list of toxic pollutants or combinations of pollutants and to set effluent standards, pretreatment standards, and prohibitions for these. Gives EPA authority to set standards more stringent than Best Available Technology (BAT) if health and ecological impacts are not mitigated.
sec. 306	Requires EPA to publish regulations establishing standards of performance for best available technologies to control discharge of pollutants.
sec. 308	Sets forth conditions for inspections, monitoring, and entry.
sec. 310	Enables EPA to act in conjunction with the Department of State and foreign governments to abate water pollution internationally.
sec. 311	Authorizes EPA to regulate and act to mitigate the discharge of oil or hazardous substances into navigable waters.
sec. 401	Requires facilities which discharge pollutants into water to be certified.
sec. 402	Establishes conditions for issuance of permits to discharge into navigable waters.
sec. 404(a)	Authorizes the Army Corps of Engineers to issue permits for the discharge of dredged or fill material into waterways at specified disposal sites.
sec. 404(b)	Authorizes EPA to prohibit the specification of any area as a disposal site if the discharge of the dredged or fill material will have an adverse effect on people or the environment.
sec. 405(a)	Prohibits disposal of sludge without a permit.
sec. 405(b)	Allows regulations to be issued setting out guidelines for acceptable methods for disposal of sewage sludge.
sec. 504	Authorizes EPA to act to stop or mitigate environmental discharges which present an imminent hazard.

Regulatory Options Available Under Statute

- Set guidelines and standards of performance for effluent limitations
- Require application of best available technology to control discharges
- Regulate discharges of hazardous substances
- Issue permits for discharge of dredged or fill material
- Prohibit discharge or hazardous dredged or fill material
- Regulation disposal of sludge

REGULATORY DEVELOPMENT

REGULATORY PROCESS

For discussion of the regulatory process within the Environmental Protection Agency, see page 233 of this publication.

EXISTING REGULATIONS

Clean Water Act	40 CFR 400

TOXICS-RELATED ACTIVITIES

The Office of Water Regulations and Standards (OWRS) has three major toxics-related programs: developing nationally uniform industrial point source effluent limitations and pretreatment standards; developing water quality criteria; and managing ambient and end-of-pipe monitoring programs. These programs address a priority list of toxic chemicals established by a 1976 consent decree with the Natural Resources Defense Council and codified in the 1977 Clean Water Act amendments. This list of 65 toxic substances includes some categories and families of substances, which was refined by EPA to an initial list of 129 specific pollutants. EPA may add to or delete from this list by a rulemaking; to date, three have been deleted.

Effluent Limitations

The major Clean Water Act mechanism to control toxic chemical discharges is nationally uniform effluent limitations for industry categories. These are technology-based, economically achievable and economically-based limitations on the discharge of specific process wastewater constituents.*OWRS is developing toxic effluent limitations for 129 consent decree toxic substances for 21 major industry categories. As of the beginning of May 1983, regulations for 13 industries have been promulgated and regulations for 15 industries have been proposed.

Water Quality Criteria

Water Quality Criteria have been promulgated for 64 of the 65 toxic substances named in the consent decree. These Water Quality Criteria set ambient concentrations acceptable for aquatic organisms and human contact. These criteria are used, in conjunction with use designations, to establish State Water Quality Standards. Violations of Water Quality Standards may result in a requirement for water quality-based effluent controls more stringent than the existing technology- and economically-based limitations.

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*These limitations are implemented via the National Pollutions Discharge Elimination System (NPDES), which is managed by the Office of Water Enforcement and Permits. Under the NPDES program, a permit incorporating any promulgated effluent limitation is written for every direct discharger to navigable waters.

Monitoring

The Office of Water Regulations and Standards is responsible for developing monitoring strategies for the 129 priority toxic substances, both end-of-pipe and in-stream. Water quality monitoring identifies water bodies where controls more stringent than the technology-based limitations are required, evaluates the progress achieved to date in water quality cleanup efforts and helps to determine the relative industrial, municipal and nonpoint source contributions of toxic pollutants to the Nation's waters.

OFFICE OF DRINKING WATER

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-5508

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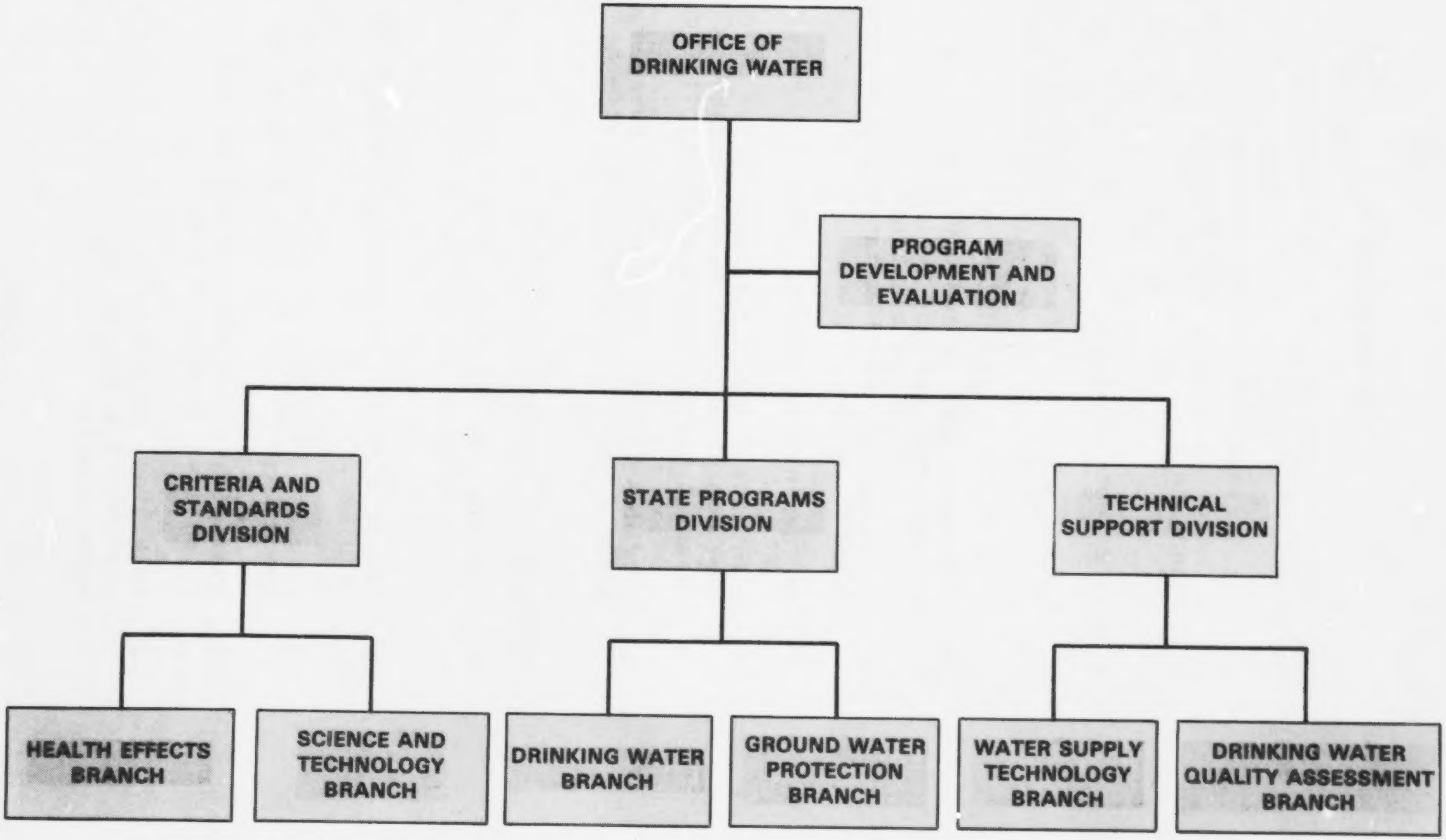
Statutory Authority page 270
Regulatory Development page 274
Toxics-Related Activities page 275

The Office of Drinking Water (ODW) is responsible for the implementation and coordination of the programs established by the Safe Drinking Water Act. As such, it establishes standards, develops regulations, policies, and guidelines for drinking water quality and treatment requisite to protect the public health and welfare. It also establishes and implements a program to protect underground sources of drinking water from endangerment by the subsurface emplacement of fluids through wells. ODW also has a mission to coordinate Agency programs from the perspective of their impact on ground water.

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF WATER AND WASTE MANAGEMENT
OFFICE OF DRINKING WATER
ORGANIZATIONAL CHART*


OFFICE OF DRINKING WATER
PROGRAM DEVELOPMENT AND EVALUATION
CRITERIA AND STANDARDS DIVISION
STATE PROGRAMS DIVISION
TECHNICAL SUPPORT DIVISION
HEALTH EFFECTS BRANCH
SCIENCE AND TECHNOLOGY BRANCH
DRINKING WATER BRANCH
GROUND WATER PROTECTION BRANCH
WATER SUPPLY TECHNOLOGY BRANCH
DRINKING WATER QUALITY ASSESSMENT BRANCH

*NOTE: A partial organization chart is shown here to highlight (in gray) those components of the Office of Drinking Water which are ordinarily involved in toxic substances activities.

ORGANIZATION

CRITERIA AND STANDARDS DIVISION

- Establishes and revises regulations and guidelines relating to primary and secondary drinking water standards.

Health Effects Branch

- Develops health effects criteria for and manages development of the Primary Drinking Water Regulations.
- Proposes research and development work necessary to the establishment of Maximum Contaminant Levels (MCLs) as well as treatment requirements and criteria for health-related contaminants in drinking water.
- Defines health-effects research needs.
- Maintains liaison with the Office of Research and Development of the EPA, and Federal and other agencies having health responsibilities.
- Provides health advisories in emergency situations where a water supply might be affected.

Science and Technology Branch

- Develops the technical and scientific rationale for treatment regulations and maximum contaminant levels.
- Establishes and revises Secondary Drinking Water Regulations.
- Develops site selection, surveillance, and operation and maintenance guidelines.
- Evaluates appropriate standards and criteria for potable wastewater reuse.
- Initiates and monitors contracts and special studies in areas of the science and technology of water supply.

- Reviews and provides informal advice with respect to direct and indirect additives to water.

STATE PROGRAMS DIVISION

- Develops and revises regulation and guidelines for State water supply programs and Underground Injection Control programs.

- Monitors regional and state implementation of State program aspects of the Safe Drinking Water Act.

Drinking Water Branch

- Develops and revises regulations, guidelines, and criteria for State public water supply programs and State grants.

- Provides guidance to, and follows the progress of, Regions and States in the monitoring and administration of progress in Primacy and Non-Primacy States.

- Coordinates the Interstate Carrier water supply program on a Regional/State/local level.

Ground Water Protection Branch

- Develops and revises regulations and guidelines for Underground Injection Control programs.

- Provides guidance to the Regions and States in the development and implementation of Underground Injection Control programs.

TECHNICAL SUPPORT DIVISION

- Provides technical assistance to the Regions and States in the areas of operation and maintenance, monitoring and surveillance, treatment technology, and manpower development programs.

- Provides technical support for the use of available treatment techniques.

- Maintains a group of experienced personnel for technical support in emergency situations.
- Plans and prepares studies of the nature and extent of contaminants in public water supplies and ground water sources.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone*	Mail Stop
Office of Drinking Water	202-382-5508	WH-550
Criteria and Standards Division	202-382-7575	WH-550
Health Effects Branch	202-382-7571	WH-550
Science and Technology Branch	202-382-3034	WH-550
State Programs Division	202-382-5522	WH-550
Drinking Water Branch	202-382-5526	WH-550
Ground Water Protection Branch	202-382-5530	WH-550
Technical Support Division	513-684-4374	26 W. St. Clair St. Cincinnati, Ohio 45268

*FTS numbers are the same

STATUTORY AUTHORITIES

The Safe Drinking Water Act

Public Law 95   42 U.S.C.§300

Under the authority of the U.S. Public Health Service, standards for potable water were first issued in 1912 in an effort to prevent the spread of communicable diseases. Over the years, these standards were modified and expanded many times. The standards set limits for chemical and biological impurities affecting human health and also recommended limits for impurities that affected appearance, taste, or odor. Although the standards applied only to water systems on interstate carriers such as trains, planes, and buses they were widely used as guidelines by most States and large cities. With the establishment of the Environmental Protection Agency in 1970, the authority to set and enforce interstate drinking water standards was transferred to EPA from the Public Health Service.

The Safe Drinking Water Act (SDWA), passed by Congress in 1974, was designed to protect public drinking water supplies by assuring that minimum national standards for the protection of human health were met. The Act, which was designated as section XIV of the Public Health Service Act, gives EPA the authority to set minimum drinking water standards for all public water systems in the Nation serving at least 25 people or having at least 15 connections. Implementation of the regulations rests primarily with the States. A State must apply for primary enforcement status (primacy) which requires that States have regulations at least as stringent as Federal standards. To date, 51 States have received primary enforcement status. EPA has enforcement responsibility only within those States not granted primacy.

The following list indicates which states have assumed primacy, and the dates of assumption.

1.	Oklahoma	04-29-77	27.	Montana	03-29-78
2.	Connecticut	05-06-77	28.	Idaho	03-29-78
3.	Louisiana	05-07-77	29.	Washington	03-29-78
4.	Mississippi	06-19-77	30.	New Mexico	04-01-78
5.	Nebraska	06-22-77	31.	Delaware	04-01-78
6.	Alabama	07-10-77	32.	West Virginia	04-01-78
7.	Arkansas	07-10-77	33.	Colorado	05-06-78
8.	Georgia	08-06-77	34.	California	06-02-78
9.	New York	09-09-77	35.	New Hampshire	08-18-78
10.	Virginia	09-09-77	36.	Trust Territory	09-09-78
11.	Iowa	09-11-77	37.	Guam	09-09-78
		08-01-82	38.	Alaska	09-22-78
12.	Minnesota	09-26-77	39.	Arizona	09-24-78
13.	Tennessee	09-30-77	40.	Rhode Island	11-22-78
14.	South Carolina	09-30-77	41.	Ohio	03-15-79
15.	Maine	10-07-77	42.	Missouri	09-22-79
16.	Hawaii	10-20-77	43.	Virgin Islands	09-22-79
17.	Kentucky	10-27-77	44.	Illinois	09-28-79
18.	Massachusetts	12-01-77	45.	New Jersey	12-30-79
19.	Texas	01-29-78	46.	Utah	02-28-79
20.	Michigan	02-01-78	47.	Puerto Rico	02-29-79
21.	Maryland	02-12-78	48.	North Carolina	03-14-80
22.	North Dakota	02-17-78	49.	Vermont	04-25-80
23.	Florida	02-17-78	50.	American Samoa	09-30-80
24.	Wisconsin	03-14-78	51.	Northern Mariana Islands	12-04-82
25.	Nevada	03-29-78			
26.	Kansas	03-29-78			

The following do not have primacy:

District of Columbia
Indiana
Oregon
Pennsylvania
South Dakota
Wyoming

OTHER

1. Iowa assumed primacy on 09-11-77 and returned primacy on 07-01-81. Redelegation occurred on 08-01-82.

Key Sections of Act--Toxics Focus

The Act is divided into four basic parts, which are further divided into subsections.

Part A--Definitions

Part A defines some basic terms relevant to the Act. Several of the more important terms include:

Primary Drinking Water Regulation. A regulation which applies to public water systems, specifying contaminants which, in the judgement of the Administrator, may have any adverse effect on human health, and specifying for each contaminant either a maximum contaminant level (MCL) or if an MCL is not economically or technologically feasible, then a treatment technique which sufficiently reduces the contaminant level.

Secondary Drinking Water Regulation. Applies to public water systems, and specifies the recommended levels for any contaminant which may affect the odor or appearance of water, thereby causing the public to discontinue using it.

Public Water System. A system which provides piped water for human consumption, and has at least 15 service connections or serves at least 25 people.

Contaminant. Any physical, chemical, biological, or radiological substances or matter in water.

Maximum Contaminant Level. The maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

Part B--Public Water Systems

sec. 1412(a)(1)	Requires the Administrator to set primary drinking water regulations.
sec. 1412(c)	Requires the Administrator to promulgate secondary drinking water regulations.
sec. 1413	Gives primary enforcement responsibility to the States allowing for Federal enforcement only in those cases where a State is unwilling or unable to enforce.

sec. 1415	Lists the conditions under which a variance may be granted.
sec. 1416	Provides for exemptions to the Act.

Part C--Protection of Underground Sources of Drinking Water

sec. 1421	Requires the Administrator to publish regulations to control underground injection of fluids which may endanger drinking water sources for public water systems.
sec. 1422	Requires the Administrator to list in the *Federal Register* each State for which a control program is necessary and directs each listed State to adopt and implement the regulations developed under section 1421.
sec.1425	Provides optional demonstration by States relating to oil and gas injection programs.

Part D--Emergency Powers

sec. 1431	Directs the Administrator, in the absence of action by State authorities, to issue orders or commence civil actions to protect public health in the event that a contaminant entering a public water system may pose an imminent or substantial hazard.

REGULATORY DEVELOPMENT

REGULATORY PROCESS

For a discussion of the regulatory process within the Environmental Protection Agency, see page 233 of this publication.

EXISTING REGULATIONS

Safe Drinking Water Act	
Interim Primary Drinking Water Regulations	40 CFR 141
Secondary Recommended Maximum Contaminant Levels	40 CFR 143
Underground Injection Control	40 CFR 124, 144, 145, 146

TOXICS-RELATED ACTIVITIES*

The Underground Injection Control Program

Part C of the Safe Drinking Water Act (SDWA) instructs the EPA to establish a national program to prevent underground injections of fluids which endanger drinking water sources. Congress intended the Underground Injection Control Program (UIC) to protect not only the ground water which already serves as a source of drinking water, but also ground water that could potentially serve as a source of drinking water in the future.

In keeping with the requirements, final regulations were promulgated in 1980 and amended in 1982 and 1983. Six complete and seven partial state programs have been approved. EPA is also about to propose direct implementation programs in 22 states.

Additives in Drinking Water

The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The agreement became effective on June 22, 1979.

The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a 'food' under the Federal Food, Drug, and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

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*Note: Included here are those activities identified as toxics-related from the information provided by each agency or office at the time of publication. It is recognized that some activities may have inadvertently been omitted. Please bring any such omissions, as well as new additions, to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

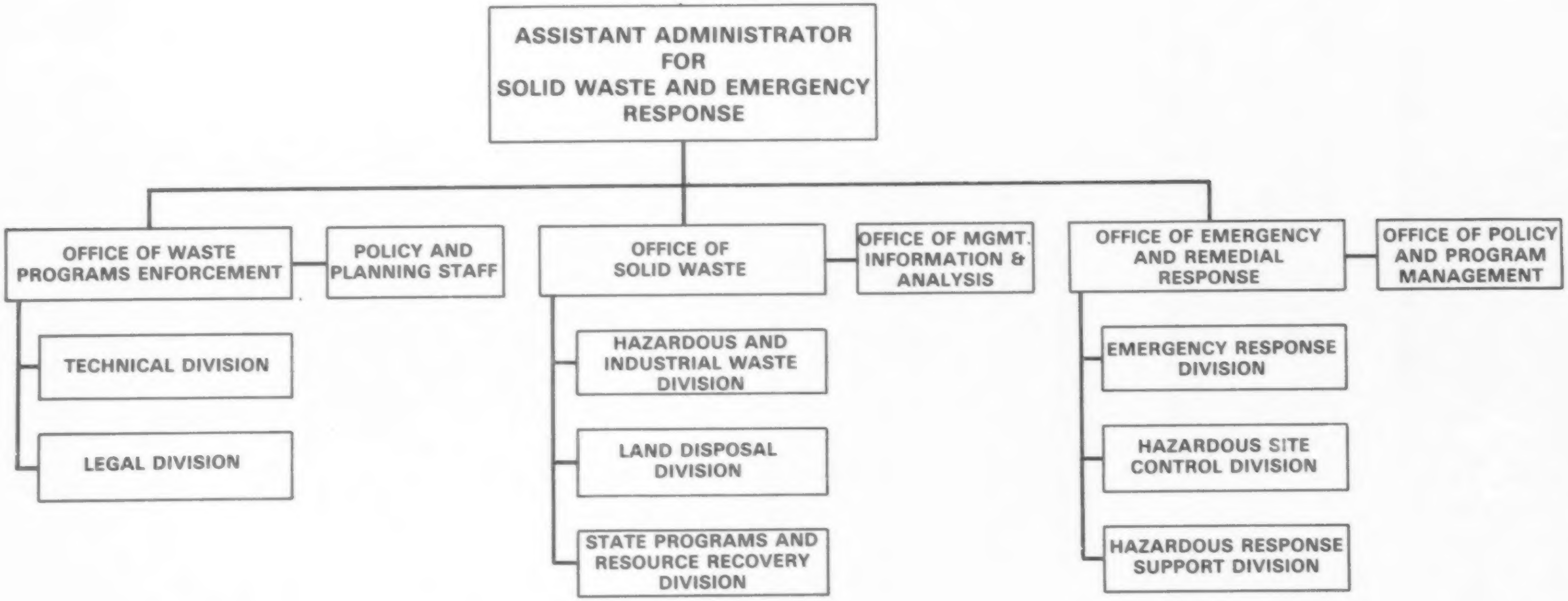
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-4610

The Office of the Assistant Administrator for Solid Waste and Emergency Response provides Agencywide policy, guidance, and direction for the Agency's solid waste and emergency response programs. In addition to managing those programs, the Assistant Administrator serves as principal adviser to the Administrator in matters pertaining to them. The Assistant Administrator's responsibilities include: (a) Program policy development and evaluation; (b) Development of appropriate hazardous waste standards and regulation; (c) Ensuring compliance with applicable laws and regulations; (d) Program policy guidance and overview, technical support, and evaluation of Regional solid waste and emergency response activities; (e) Development of programs for technical; programmatic, and compliance assistance to States and local governments; (f) Development of guidelines and standards for the land disposal of hazardous wastes; (g) Analyses on the recovery of useful energy from solid waste; and (h) Development and implementation of a program to respond to uncontrolled hazardous waste sites and spills (including oil spills).

Two offices within the Office of Solid Waste and Emergency Response will be highlighted in this publication. They are the Office of Solid Waste and the Office of Emergency and Remedial Response.

OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE


ASSISTANT ADMINISTRATOR FOR SOLID WASTE AND EMERGENCY RESPONSE
OFFICE OF WASTE PROGRAMS ENFORCEMENT
POLICY AND PLANNING STAFF
TECHNICAL DIVISION
LEGAL DIVISION
OFFICE OF SOLID WASTE
OFFICE OF MGMT. INFORMATION & ANALYSIS
HAZARDOUS AND INDUSTRIAL WASTE DIVISION
LAND DISPOSAL DIVISION
STATE PROGRAMS AND RESOURCE RECOVERY DIVISION
OFFICE OF EMERGENCY AND REMEDIAL RESPONSE
OFFICE OF POLICY AND PROGRAM MANAGEMENT
EMERGENCY RESPONSE DIVISION
HAZARDOUS SITE CONTROL DIVISION
HAZARDOUS RESPONSE SUPPORT DIVISION

OFFICE OF SOLID WASTE

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-4627

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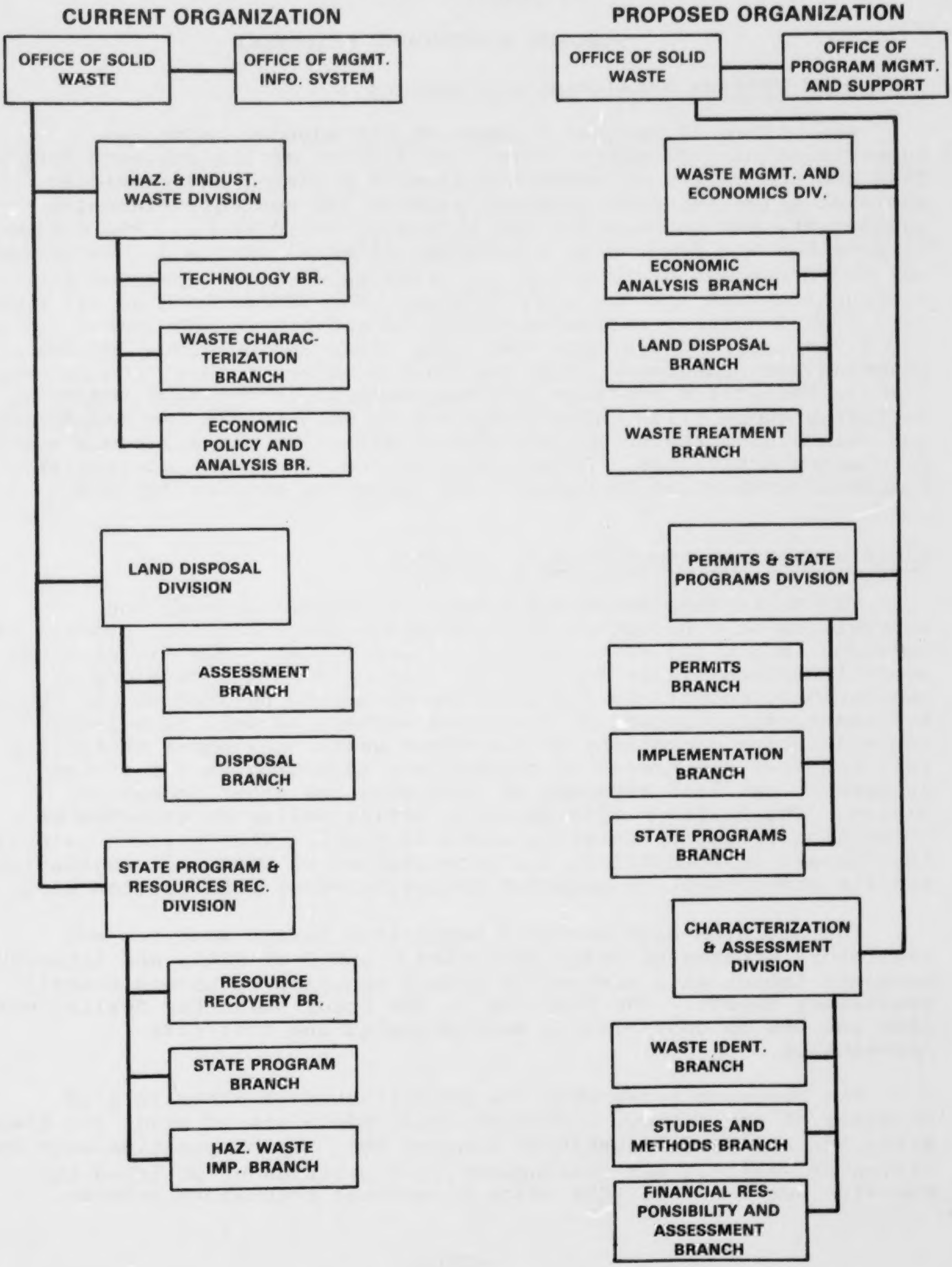
Regulatory Development..........Page 294
Toxics-Related Activities.......Page 295

The Office of Solid Waste is responsible for implementing the Resource Conservation and Recovery Act of 1976 (RCRA). As such, the Office has lead responsibility for the development of all regulations and guidelines under RCRA as well as the establishment of basic policies for technical and financial assistance, public participation, and a number of other programs.

OFFICE OF SOLID WASTE


CURRENT ORGANIZATION
OFFICE OF SOLID WASTE
OFFICE OF MGMT. INFO. SYSTEM
HAZ. & INDUST. WASTE DIVISION
TECHNOLOGY BR.
WASTE CHARACTERIZATION BRANCH
ECONOMIC POLICY AND ANALYSIS BR.
LAND DISPOSAL DIVISION
ASSESSMENT BRANCH
DISPOSAL BRANCH
STATE PROGRAM & RESOURCES REC. DIVISION
RESOURCE RECOVERY BR.
STATE PROGRAM BRANCH
HAZ. WASTE IMP. BRANCH
PROPOSED ORGANIZATION
OFFICE OF SOLID WASTE
OFFICE OF PROGRAM MGMT. AND SUPPORT
WASTE MGMT. AND ECONOMICS DIV.
ECONOMIC ANALYSIS BRANCH
LAND DISPOSAL BRANCH
WASTE TREATMENT BRANCH
PERMITS & STATE PROGRAMS DIVISION
PERMITS BRANCH
IMPLEMENTATION BRANCH
STATE PROGRAMS BRANCH
CHARACTERIZATION & ASSESSMENT DIVISION
WASTE IDENT. BRANCH
STUDIES AND METHODS BRANCH
FINANCIAL RESPONSIBILITY AND ASSESSMENT BRANCH

PROPOSED FUNCTIONAL STATEMENT

Office of Program Management and Support

The Office of Program Management and Support under the supervision of a Director, serves as a point of liaison with OSWER, OPRM and the Office of Administration in securing and providing administrative services, budget planning and control, financial management, and support for the Office of Solid Waste. The Office is responsible for developing all budget material (OMB and Congressional) for the Hazardous Waste Media and develops workload analyses in conjunction with the Regional Offices. The Office handles all budget execution functions including contracts and grants management for all OSW divisions, and develops operating plans and guidance for OSW planning and management, then monitors progress to meet the guidance given. The Office develops all responses to information requests, including those filed under FOIA, and is responsible for developing and maintaining the docket to support all solid and hazardous waste regulatory activities. Plans and conducts management activities. Provides administrative support and personnel service for OSW.

WASTE MANAGEMENT AND ECONOMICS DIVISION

The Waste Management and Economics Division, under the supervision of a Director, is responsible for a national program of hazardous and solid waste regulation under RCRA. The Division has overall responsibility for section 3004 of RCRA and develops regulations, guidelines and guidance documents related to the storage, treatment, and disposal of hazardous wastes, as well as selected administrative operations at hazardous waste management facilities. This requires assessment of appropriate technologies for storage, treatment, and land disposal of hazardous and other industrial wastes. The Division also develops Office policy on groundwater protection issues relative to waste disposal. The Division maintains the primary responsibility for promulgation of waste oil regulations, and for procurement of recycled materials under RCRA section 6002.

The Division also prepares regulatory impact analyses and regulatory strategies under Subtitles C and D of RCRA, and integrates economic impact data with other Agency programs to assess overall regulatory impact. The Division is the focal point for dealing with OPRM and OMB on cost/benefit methodologies and cost/risk assessments.

The Division integrates its activities with other related programs of the Agency, including those administered under the Clean Water Act and Toxic Substances Control Act. In cooperation with the Office of Research and Development, the Division establishes the research needs of the RCRA waste management regulatory program.

Waste Treatment Branch

The Waste Treatment Branch has primary responsibility for the assessment of technologies and promulgation of regulations, guidelines, and guidances, for the storage, treatment, incineration, and recovery of hazardous wastes.

Specifically, the Branch has responsibility for development and amendments to the regulatory program under section 3004 of RCRA except for land disposal. This includes developing overall administrative requirements and integrating technical and financial information developed within the Branch and elsewhere in OSW into regulations for storage, treatment, and incineration facilities for hazardous waste. Also included is the development of appropriate operating and design manuals, monitoring manuals, training manuals, and other industry specific guidance and guidelines to accompany the regulations.

The Waste Treatment Branch assesses the performance, availability, and costs of technologies for storage, treatment, incineration, and recovery of hazardous or industrial wastes in order to develop recovery, processing and treatment options for incorporation into regulations or guidelines. The Branch is also responsible for special waste studies mandated by Congress (e.g. mining and utility wastes).

The Branch has responsibility for assessment of technologies and development of a program for waste oil pursuant to the Solid Waste Disposal Act Amendments of 1980 and the Used Oil Recycling Act of 1980.

The Branch has responsibility for procurement guidelines under section 6002 of RCRA, for Federal Agencies to revise purchase specifications to include recovered materials in products.

Land Disposal Branch

The Land Disposal Branch is responsible for the development of land disposal regulations under RCRA section 3004, as well as criteria and guidelines to control the land disposal of non-hazardous waste authorized by Subtitle D of RCRA. The Branch prepares regulations and technical guidance related to issues of land disposal facility location, design, operations, and closure. In conjunction with the Office of Research and Development, the Branch assesses appropriate technologies, including performance availability and costs, for land disposal facilities. Units of concern are landfills, land treatment units, waste piles, and surface impoundments. The Branch develops groundwater quality criteria, standards and monitoring requirements for incorporation in RCRA rules and guidance documents and ensures that these are compatible with the groundwater protection policies of the Agency. The Branch also develops regulations and guidances for other environmental and health concerns, including air emissions control and surface water, soils, and food-chain crops protection.

Economic Analysis Branch

The Economic Analysis Branch is responsible for preparing regulatory impact analyses and strategies for regulating hazardous wastes that consider the trade-offs between cost and risk. The Branch coordinates and prepares regulatory impact analyses required by Executive Order 12291 and regulatory flexibility analyses as mandated by the Regulatory Flexibility Act (RFA). These analyses involve detailed assessments of the costs and benefits of regulatory and non-regulatory strategies, as well as complex analyses of the impacts of each alternative strategy on industry and the society as a whole. The Branch plans, develops and prepares these analyses using analytical frameworks, economic, financial, mathematical, and risk modeling techniques, data and information developed in the Branch, elsewhere in the Office, by Branch contractors and in the academic community. The Branch is also the focal point for dealing with OPRM, OMB, other Agencies and institutions on cost/benefit methodologies and cost/risk assessments.

PERMITS AND STATE PROGRAMS DIVISION

The Permits and State Programs Division, under the supervision of a Director, is responsible for the nationwide implementation of a program to control hazardous wastes, including the permitting of facilities and the authorization of States to operate their programs in lieu of a federal program. As such the Division is the Headquarters focal point for interaction with State and local governments in cooperation with the EPA Regional Offices. The

Division provides oversight, guidance and support for Regions and States implementing programs in solid and hazardous waste under Subtitles C and D of the Resource Conservation and Recovery Act (RCRA). It develops regulations for what constitutes an equivalent State program under the Act for the purposes of delegating the hazardous waste program; develops transporter and generator recordkeeping and reporting regulations in cooperation with DOT; and provides guidance on solid and hazardous waste requirements relative to State/EPA agreements. The Division assists the Regional Offices in the implementation of the solid and hazardous waste programs, through the State Planning Guidelines and the open dump inventory for Subtitle D; the manifest, or cradle-to-grave tracking system, and automated data processing system covering hazardous waste facilities and handlers affected by RCRA. The Division has overall responsibility for the development, administration and implementation of the hazardous waste permit program. This responsibility includes the development of permit processing regulations, establishment and interpretation of procedures for RCRA permit issuance, the provision of Regional guidance for technical content, review, and evaluation of RCRA permits; and the provision and coordination of technical assistance to the Regions on permitting actions. The Division is responsible for the development and management of data tracking and reporting systems (including ADP systems) needed for Regional and Headquarters implementation of the hazardous waste regulatory system. The Division is responsible for implementing the Agency's municipal, industrial, and hazardous waste resource recovery program. The Division has the primary responsibility for regulations, guidelines and guidance documents related to sections 2003, 4002, 4003, 4005, 4006, 4007, 4008, 4009, 3002, 3003, 3005, 3006, 3010, and 3011, of RCRA.

State Programs Branch

The State Programs Branch is responsible for the nationwide implementation, through State programs, of solid waste policies and procedures. The Branch provides the Office's oversight, guidance, and support to State and local governments, in cooperation with the EPA Regional Offices, for implementation of State programs responsive to RCRA Subtitles C and D. The Branch has primary responsibility for regulations, guidelines, and guidance documents related to sections 4002, 4003, 4005, 4007, 4008, 4009, 3006, and 3011 of RCRA.

The Branch develops and oversees the implementation of regulations for States' preparation and carrying out of solid waste management plans. State activities in this area requiring monitoring and evaluation by the Branch include technical and institutional aspects of State plans and procedures to identify, upgrade, and close open dumps; development of regulatory powers; planning, permitting, and inspection of facilities, including those for resource recovery and coordination of regional planning and implementation. The Branch develops and manages the implementation of regulations defining "equivalent" programs under RCRA for purposes of State delegation of the hazardous waste program. The Branch assesses technical and institutional aspects of State programs to control hazardous wastes from cradle-to-grave, including permitting, manifest, and planning programs. The Branch provides guidance on solid and hazardous waste requirements relative to State-EPA agreements and receipt of federal financial assistance.

Permits Branch

The Permits Branch is responsible for the development and implementation of the Hazardous Waste Permit program. This responsibility includes development of the regulations necessary to support the RCRA permitting program, and the establishment and interpretation of procedures used by the Regions and in State programs in permitting hazardous waste treatment, storage and disposal facilities. The Branch develops national permitting strategies, provides guidance for technical content, review and evaluation of RCRA permits and evaluates achievement of permit targets. The Branch coordinates technical assistance to the Regions on permitting actions and is responsible for the conduct and overall management of Permit Assistance Teams (PATs). Using in-house expertise and contractual support, the Branch provides a variety of technical support and policy guidance necessary for the Regional Offices to implement the permitting program. A national contract to provide Regions with technical services for hazardous waste facility permitting is managed by this Branch. The Branch is also responsible for implementing the Agency's municipal, industrial, and hazardous waste resource recovery program.

Implementation Branch

The Implementation Branch provides support and guidance for the implementation of Subtitle C of RCRA. This includes responsibility for the development and management of data tracking and reporting systems (including ADP systems) needed for Regional Office and Headquarter's implementation of the hazardous waste regulatory program. It also includes responsibility for the development and management of systems which will assist the office to evaluate the implementation of RCRA and regulations; and responsibility for coordinating the development of the hazardous waste data management system with other Agency ADP systems. The Branch is responsible for the management of the hazardous waste industry assistance program; and development and implementation of the Agency's industrial waste exchange program. The Branch also is responsible for the development of regulations as well as guidance and assistance in the implementation of the generator and transporter regulations Parts 262 and 263. The program is responsible for coordinating RCRA transportation regulatory development and implementation with the Department of Transportation. The Branch also develops and implements regulations and procedures for hazardous waste notification under section 3010 of RCRA.

CHARACTERIZATION AND ASSESSMENT DIVISION

The Characterization and Assessment Division, under the supervision of a Director, is responsible for developing regulations under section 3001 of RCRA to determine which wastes are hazardous, and managing programs to sample and characterize wastes, establish waste testing protocols, and to list or delist wastes as hazardous. The Division also has responsibility for developing the financial responsibility regulations required by section 3004, establishing the regulatory and other requirements for the CERCLA post-closure liability fund, as well as other financing and liability options associated with new legislative proposals. The Division coordinates all data and assessment activities, supervises the conduct of all surveys of the regulated community, manages the preparation of clearance packages and prepares the Office Information Collection Budget for OMB.

The Division also develops regulations for special classes of generators of hazardous waste, and manages a complex program for studying the waste streams and management practices of selected industries.

The Division integrates its activities with related other programs of the Agency, including those administered under the Clean Water Act and Toxic Substances Control Act. In cooperation with the Office of Research and Development, the Division establishes research needs related to waste characterization and listing.

Waste Identification Branch

The Waste Identification Branch develops regulations under RCRA section 3001 which defines hazardous waste. The Branch is responsible for amendments and revisions to the regulations in response to petitions, Congressional mandate, or as a function of internal review and analysis; examples include small quantity generator regulatory changes, identification of waste to be restricted from land disposal, amended definition of solid waste and regulation of recycled materials (from hazardous waste). As required, these changes will be coordinated with other OSW organizational units. The Branch responds to petitions to exclude from regulation particular wastes from specific facilities. The Branch develops and makes technical determinations as to hazardous waste characteristics and hazardous waste lists, and evaluations for wastes to be removed from such lists. The Branch manages the technical studies necessary for the section 3001 program and also prepares technical support for Agency use in legal defense of the regulations.

The Branch cooperates with the Offices of Toxic Substances, Water, and Research and Development to assure that the section 3001 program is consistent with their chemical regulation programs.

Studies and Methods Branch

The Studies and Methods Branch has the responsibility for studies related to the waste generation, recovery, and overall management practices of various industries.

The Branch investigates and validates hazardous waste sampling methods, develops test protocols and evaluates chemical and biological tests for applicability to regulatory needs. Through contracts, cooperation with technical organizations and laboratories, and liaison with industry, the Branch develops the technical information base on industrial waste streams needed to define criteria for and characteristics of hazardous waste.

The Branch cooperates with the Office of Research and Development to assure that the RCRA methods development program is consistent with ORD's test methodology program. The Branch serves as the focal point for coordination with ORD for divisional research needs and implementation.

The Studies and Methods Branch has responsibility for the quality assurance oversight program for the Office of Solid Waste.

Financial Responsibility and Assessment Branch

The Branch develops state-of-the-art reports and policy position papers on waste management issues such as Federal and State strategies for hazardous waste facility development and siting. The Branch provides liaison and information on legislative and policy analysis aspects of solid, industrial and hazardous waste management to Agency and Interagency groups to State and local governments, to OMB and the Congress. It evaluates the impact, effectiveness and efficiency of the hazardous waste program for internal management, as well as for the Office of Management and Budget and the Congress. The Branch develops and implements a post-closure liability program as required under the Comprehensive Environmental Response, Compensation and Liability Act of 1980. It coordinates data assessment activities for the Office of Solid Waste to meet regulatory needs as well as the requirement of the Paperwork Reduction Act, and develops the Office Information Collection Budget. The Branch evaluates proposed legislation, and develops legislative initiatives for the Office on solid and hazardous waste management topics.

The Branch is also the focal point for development of financial responsibility requirements of RCRA section 3004 regulations and of financing and liability options associated with new legislative proposals. Alternatives for funding solid waste management programs and for implementation and administrative systems are analysed by the Branch.

ORGANIZATION*

STATE PROGRAMS AND RESOURCE RECOVERY DIVISION

- Responsible for the nationwide implementation of a program to control hazardous wastes, control the land disposal of all solid wastes, and conserve resources through the recovery of solid and hazardous wastes.

Hazardous Waste Implementation Branch

- Provides guidance and support for the implementation of Subtitle C of RCRA.
- Develops standards and guidance for hazardous waste generators and transporters.
- Responsible for the hazardous waste permit and notification programs.

LAND DISPOSAL DIVISION

- Responsible for a national program to control and regulate the land disposal of all solid and hazardous waste.

Assessment Branch

- Establishes ground water quality criteria and sets up policies for protecting ground water supplies against the adverse effects of land disposal.

Disposal Branch

- Develops criteria, guidelines, and regulations for controlling the land disposal of solid and hazardous wastes, including sewage sludge.
- Assesses the technologies available for land disposal and application of wastes.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Develops, in cooperation with the Office of Research and Development (EPA) and the Technology Branch of the OSW, technical performance standards for land disposal alternatives.

HAZARDOUS AND INDUSTRIAL WASTE DIVISION

- Develops regulations for the characterization and control of hazardous waste.
- Coordinates a national program of technology and environmental analysis and economic assessment for hazardous and solid wastes.
- Maintains liaison with the industrial community and the Office of Pesticides and Toxic Substances (EPA).

Waste Characterization Branch

- Manages technical studies, provides technical support in regulatory matters, and makes determinations on hazardous waste characteristics and lists.
- Responsible for developing and validating hazardous waste sampling methods, designing test protocols, and evaluating chemical and biological tests for their application to the listing and characterization process.
- Develops information on waste streams used in defining criteria for hazardous waste.

Industry Technology Branch

- Promulgates regulations and guidelines for the storage, treatment, incineration, and recovery of hazardous wastes. In developing the regulations, the Branch studies the performance, availability, and costs of various technological methods.
- Assesses industrial solid waste management practices.
- Develops Federal guidelines for procurement of products containing recycled materials.

Economic and Policy Analysis Branch

- o Prepares economic assessments and environmental impact statements.

- o Economic analyses focus on the economic impact of hazardous and solid waste regulatory programs and include both industrial and public facilities.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone*	Mail Stop
Office of Solid Waste	202-382-4627	WH-562
Land Disposal Division	202-382-4658	WH-564
Assessment Branch	202-382-4658	WH-564
Disposal Branch	202-382-4658	WH-564
State Programs and Resource Recovery Division	202-382-4756	WH-563
Hazardous and Industrial Waste Division	202-382-4746	WH-565
Waste Characterization Branch	202-382-4770	WH-565
Industry Technology Branch	202-382-4761	WH-565
Economic Analysis Branch	202-382-4646	WH-565

*FTS numbers are the same

STATUTORY AUTHORITIES

The Resource Conservation and Recovery Act of 1976
Public Law 94-580 48 U.S.C. § 6901

Passage of the Resource Conservation and Recovery Act of 1976 (RCRA) updated and amended the Solid Waste Disposal Act of 1965. The principal goal of RCRA is to protect public health and the environment by controlling the disposal of solid waste and regulating the management and handling of hazardous waste materials. In addition, the Act is designed to promote the conservation of natural resources through the recovery of usable energy and materials. RCRA authorizes the Environmental Protection Agency to regulate hazardous wastes from their generation to disposal; to foster establishment of regulatory programs in the States for controlling the disposal of solid wastes on land and prohibiting the use of open dumps; and to assist in developing national conservation and recovery policies.

Key Section of Act--Toxics Focus

sec. 1008	Directs the Administrator to develop and publish criteria for solid waste management.
sec. 3001	Authorizes the development of criteria for identifying hazardous wastes.
sec. 3002	Authorizes the development of standards regulating the generators of hazardous wastes.
sec. 3003	Authorizes the development of standards governing the transportation of hazardous wastes.
sec. 3004	Authorizes the development of standards for the treatment, storage, and disposal of hazardous wastes.
sec. 3005	Authorizes the issuance of permits for facilities for treatment, storage, and disposal of hazardous waste.
sec. 3006(a)	Directs the Administrator to promulgate guidelines to assist the States in developing their own hazardous waste programs.
sec. 3006(b)	Authorizes the States to administer their approved programs.
sec. 3007	Grants the Administrator authority to inspect hazardous waste facilities.
sec. 4004	Authorizes development of criteria for classification of sanitary landfills.
sec. 4005(b)	Requires an inventory of all "open dump" disposal sites in the United States.
sec. 4005(c)	Requires the closing or upgrading of those sites which do not meet the sanitary landfill criteria.
sec. 7003	Directs the Administrator to bring suit or take other legal action when solid or hazardous wastes present a danager to public health or the environment.

Regulatory Options Available Under Statute

- Authorizes the Environmental Protection Agency to develop, and the States to enforce, EPA standards governing the generation, transportation, treatment, storage, and disposal of hazardous wastes.
- Authorizes States to establish programs for the closing or upgrading of open dumps and directs States to include these programs within their Solid Waste Management plan.

REGULATORY DEVELOPMENT PROCESS

REGULATORY PROCESS

For a discussion of the regulatory process within EPA, see page 233 of this publication.

EXISTING REGULATIONS

Resource Conservation and Recovery Act		40 CFR
		40 CFR 240-267
	permitting	40 CFR 271-272
		40 CFR 124

TOXICS-RELATED ACTIVITIES*

Hazardous Waste Management Program

Under Subtitle C (Hazardous Waste Management) the main effort to date has focused on the development of regulations for hazardous wastes from the point of generation through their ultimate disposal. The following regulations were issued in 1980.Hazardous Waste

Criteria--Indentification and Listing--RCRA 3001. These regulations define wastes that will be controlled under the nationwide Hazardous Waste Management Program. Criteria are provided to identify characteristics of hazardous wastes, based on ignitability, corrosiveness, reactivity, and toxicity. Also included are testing procedures to determine whether a waste meets the described characteristics. The regulation also lists certain hazardous wastes and processes which are presumed to generate hazardous wastes. Means are also provided for demonstration of noninclusion in the Subtitle C system.

Standards for Generators of Hazardous Wastes--RCRA 3002. This regulation establishes national standards for generators of hazardous wastes, covering such items as recordkeeping, containerization and labeling, waste identification, and reporting. This regulation also contains provisions for a hazardous waste manifest system.

Standards for Transporters of Hazardous Wastes--RCRA 3003. These national standards require transporters of hazardous waste to ship only properly labeled containers and only to permitted facilities.

Standards for Hazardous Waste Treatment Storage and Disposal Facilities-RCRA 3004. Hazardous waste management facilities will be required to meet certain standards of administration, financial responsibility, and technical performance regarding operating procedures, location, and design. These standards contain provisions to protect surface water, ground water, and air quality.

Permit Regulations for Hazardous Waste Treatment, Storage, and Disposal Facilities--RCRA 3005 and Guidelines for State Hazardous Waste Programs--RCRA 3006. As part of EPA's Consolidated Permit

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have inadvertently been omitted. If you are aware of any such omissions or new additions, please bring them to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

Regulations, these regulations establish a permit program to assure uniform State (or EPA) control of hazardous waste management facilities and assist States in developing their own hazardous waste regulatory programs. The guidelines also specify minimum requirements States must meet in order to be authorized by EPA to implement these programs.

Solid Waste Management--RCRA Subtitle D. Wastes not classified as hazardous or exempt from Subtitle C because of low generation rates (under section 3001) are disposed of in sites regulated under Subtitle D (State or Regional Solid Waste Plans) of RCRA. While not considered hazardous under the definition of the Act, many of the wastes disposed of in these facilities nonetheless have the potential for creating hazardous environmental conditions. To ensure the safe disposal of these wastes, the Act requires the closure of upgrading of all open dumps under section 4005 and requires EPA to issue Criteria for the Identification of Sanitary Landfills under section 4004. Section 4005 also requires that all disposal facilities be inventoried and a determination made as to whether they meet the Landfill Criteria. Those facilities not meeting the criteria are classified as open dumps and therefore must be closed or upgraded. The Landfill Criteria became effective September [illegible], 1979.

OFFICE OF EMERGENCY AND REMEDIAL RESPONSE

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-2180

Organization.....................page 301
Statutory Authority..............page 306
Toxics-Related Activities........page 310

The Office of Emergency and Remedial Response ("Superfund") is responsible for implementing the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CECLA). As such, the Office has lead responsibility to protect the general public and the environment from accidental release of hazardous substances and for the evaluation and prioritization of all known hazardous waste sites.

OFFICE OF EMERGENCY AND REMEDIAL RESPONSE

REMEDIAL PROGRAM

The Remedial Program is charged with conducting a comprehensive effort to evaluate all known hazardous waste sites, to establish priorities for remedial response, and to undertake the appropriate remedy at as many sites as possible.

Through the 103(c) notification process mandated by CERCLA and other efforts by the Regional Offices, EPA has obtained information on over 15,000 uncontrolled hazardous waste sites. This site data is contained in an automated data system known as ERRIS, Emergency and Remedial Response Information System. The Regions are now in the process of screening and assessing these sites in ERRIS to determine the nature and severity of the problems they present. To date, the Regions have conducted preliminary assessments at over 5,000 sites and on-site inspections at over 2,000 sites. Of these, 2,400 sites have been determined to require no further action.

EPA is undertaking more extensive site investigations including sampling, lab analysis, and expert technical assessments, at the most serious of these sites. The data from these sites investigations are then used in the Hazard Ranking System to evaluate the relative threats to the public and environment. The sites with the highest hazard-ranking scores have been published as the proposed National Priorities List of 419 specified by CERCLA §105 and are eligible for fund-financed cleanup, as well as enforcement actions under CERCLA.

In order to get the program underway as quickly as possible, EPA used available information and a prototype hazard-ranking system to publish an Interim Priority List of 115 sites in October, 1981, ten months after enactment of Superfund. In July, 1983, EPA added another 45 sites to the Interim List.

The National Priorities List was proposed in December, 1982, after the Agency and the States had investigated over 1100 sites and scored 709 sites. The comment period closed February 28, after EPA had received over 250 comments, totaling approximately 8,000 pages. The National Priorities List is scheduled to be made final in June. The list is to be updated every three or four months as cleanup actions are completed and additional sites are scored.

Being on the National Priorities List does not mean that a site will automatically receive fund-financed clean-up. Current agency policy requires that an attempt be made to secure clean-up by the private party before fund-financed clean-up is initiated. If negotiations with the responsible party are unsuccessful, EPA must enter into an agreement with the State which specifies the roles EPA and the States will have in implementing the cleanup. If the State is willing to take the lead in managing the project, a cooperative agreement is signed. If the State is not willing to take the lead, it becomes a Federal lead project and a State Contract is signed. In either case, the State must provide assurances of its required cost share of 10% (or at least 50% if the site is publicly owned).

After a cooperative agreement or contract is signed, remedial site work can begin. Remedial investigations and feasiblity studies are conducted for each site to characterize the problem and to evaluate the relative merits of various proposed remedies. This work is followed by design and implementation of the remedy that is selected as the most cost-effective. The entire process is usually subdivided into several "operable units" and may take from 36-44 months.

While the work at sites is conducted by contractors, the Army Corps of Engineers has been selected to manage work at Federal-lead sites. The Corps may also provide technical assistance during the remedial investigation and feasibility study.

EPA estimates that Trust Fund monies are sufficient to fund remedial actions at about 170 sites. This is based on the following estimate of average site costs:

Remedial Investigations/ Feasibility Study	$ 800,000
Design	$ 340,000
Implementation	$4,600,000
Initial Remedial Measures (Shorter term remedial actions to stabilize site conditions)	$ 260,000
TOTAL	$6,000,000

EMERGENCY RESPONSE PROGRAM

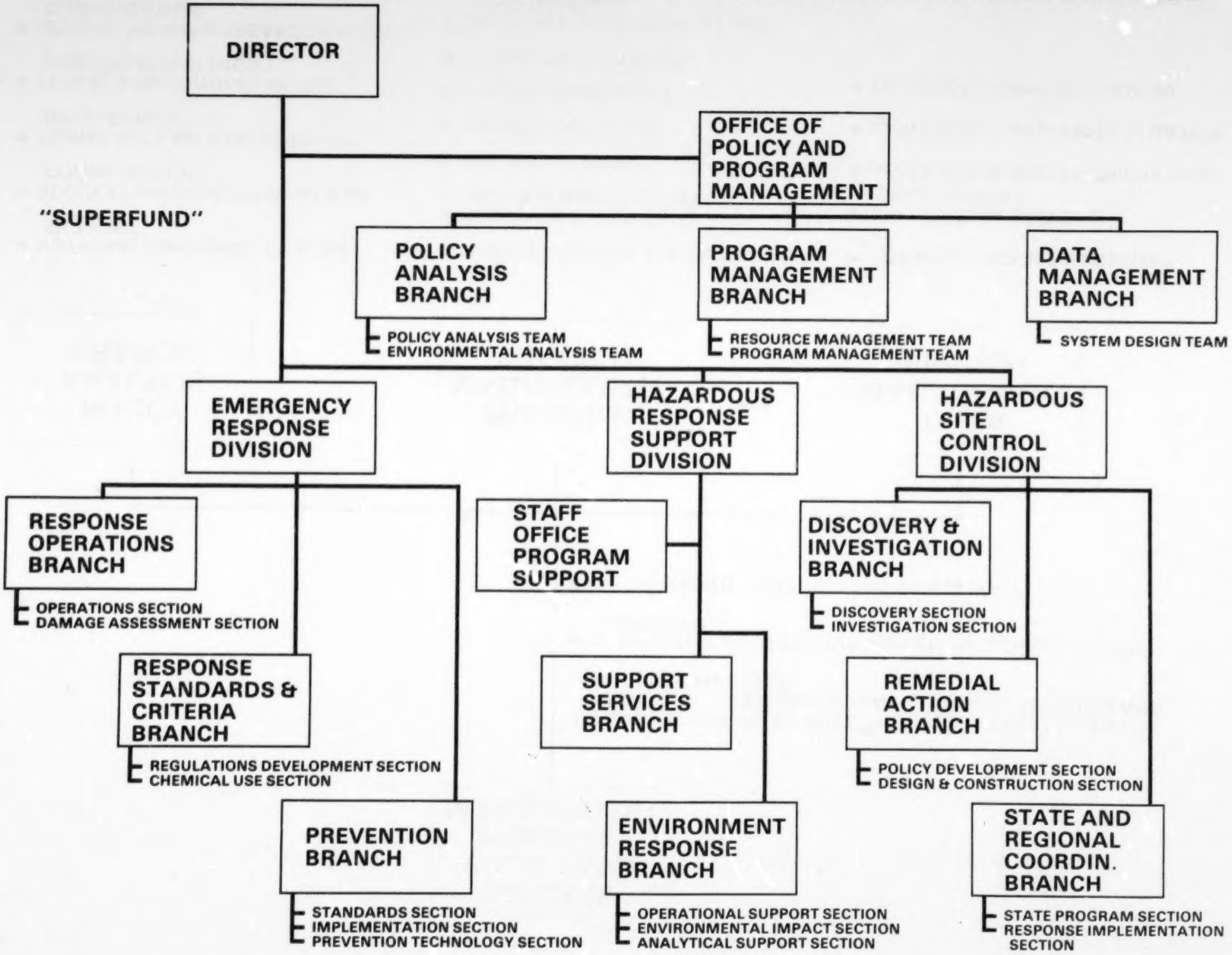
The goal of this program is to protect the general public and the environment from the hazards associated with accidental release of oil and hazardous substances. A Federal capability is maintained to receive notifications of releases, and to direct response at incidents where the responsible party was unidentifiable, refused to clean up, or was incapable of adequate removal, and the State/local authorities lacked the necessary expertise, equipment, or funding.

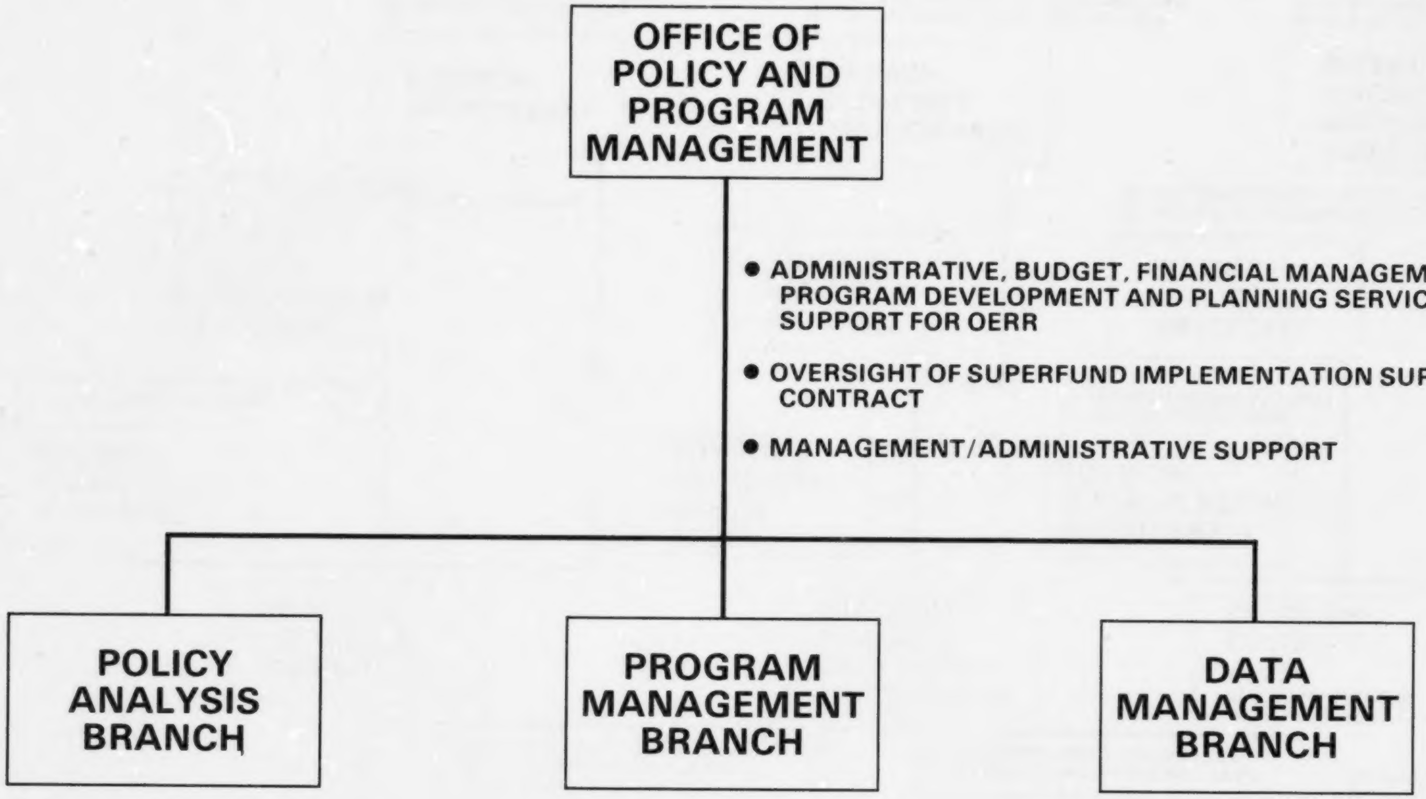
A 24-hour capability is maintained to receive and screen notifications of over 7,000 oil spills and 3,000 releases of hazardous substances per year. Each notification is assessed for potential threat to public health and the environment, and a determination is made as to whether response is appropriate by EPA, State/local authorities, or the USCG. The EPA is responsible for inland releases and the USCG responds to releases in coastal waters.

The Regions maintain a capability for responding on-scene to 120 major oil spill incidents which require expenditure of CWA 311(k) funds, and 65 major hazardous release incidents requiring CERCLA expenditures. At these incidents, an EPA On-Scene Coordinator (OSC) assesses the situation, develops a mitigative action plan, arranges for cleanup contractor support, and oversees the response. The average cost of these removal actions is about $250,000.

The Regions also respond on-scene to 400 oil spills and 400 hazardous release incidents, where cleanup is directed by State/local authorities or the responsible party, and expenditure of Federal Funds is not needed. State/local expertise and cooperation is most effectively gained by their joint participation in removal operations. These joint operations improve State/local response capabilities, provide incentive for State/local authorities to take more removal responsibilities, and improve State/Federal cooperation. By assisting on-scene, Regional OSCs transfer response technology in areas such as safety procedures, mitigative techniques, and appropriate disposal technology. A Federal presence on-scene is also the major incentive for adequate cleanup by the responsible party, and the responsible party frequently relies on technical advice from the OSCs in selecting and implementing appropriate response technology.

EPA/OSWER OFFICE OF EMERGENCY AND REMEDIAL RESPONSE


DIRECTOR
"SUPERFUND"
OFFICE OF POLICY AND PROGRAM MANAGEMENT
POLICY ANALYSIS BRANCH
POLICY ANALYSIS TEAM
ENVIRONMENTAL ANALYSIS TEAM
PROGRAM MANAGEMENT BRANCH
RESOURCE MANAGEMENT TEAM
PROGRAM MANAGEMENT TEAM
DATA MANAGEMENT BRANCH
SYSTEM DESIGN TEAM
EMERGENCY RESPONSE DIVISION
RESPONSE OPERATIONS BRANCH
OPERATIONS SECTION
DAMAGE ASSESSMENT SECTION
RESPONSE STANDARDS & CRITERIA BRANCH
REGULATIONS DEVELOPMENT SECTION
CHEMICAL USE SECTION
PREVENTION BRANCH
STANDARDS SECTION
IMPLEMENTATION SECTION
PREVENTION TECHNOLOGY SECTION
HAZARDOUS RESPONSE SUPPORT DIVISION
STAFF OFFICE PROGRAM SUPPORT
SUPPORT SERVICES BRANCH
ENVIRONMENT RESPONSE BRANCH
OPERATIONAL SUPPORT SECTION
ENVIRONMENTAL IMPACT SECTION
ANALYTICAL SUPPORT SECTION
HAZARDOUS SITE CONTROL DIVISION
DISCOVERY & INVESTIGATION BRANCH
DISCOVERY SECTION
INVESTIGATION SECTION
REMEDIAL ACTION BRANCH
POLICY DEVELOPMENT SECTION
DESIGN & CONSTRUCTION SECTION
STATE AND REGIONAL COORDIN. BRANCH
STATE PROGRAM SECTION
RESPONSE IMPLEMENTATION SECTION



OFFICE OF POLICY AND PROGRAM MANAGEMENT

- ADMINISTRATIVE, BUDGET, FINANCIAL MANAGEMENT, PROGRAM DEVELOPMENT AND PLANNING SERVICES AND SUPPORT FOR OERR
- OVERSIGHT OF SUPERFUND IMPLEMENTATION SUPPORT CONTRACT
- MANAGEMENT/ADMINISTRATIVE SUPPORT

POLICY ANALYSIS BRANCH

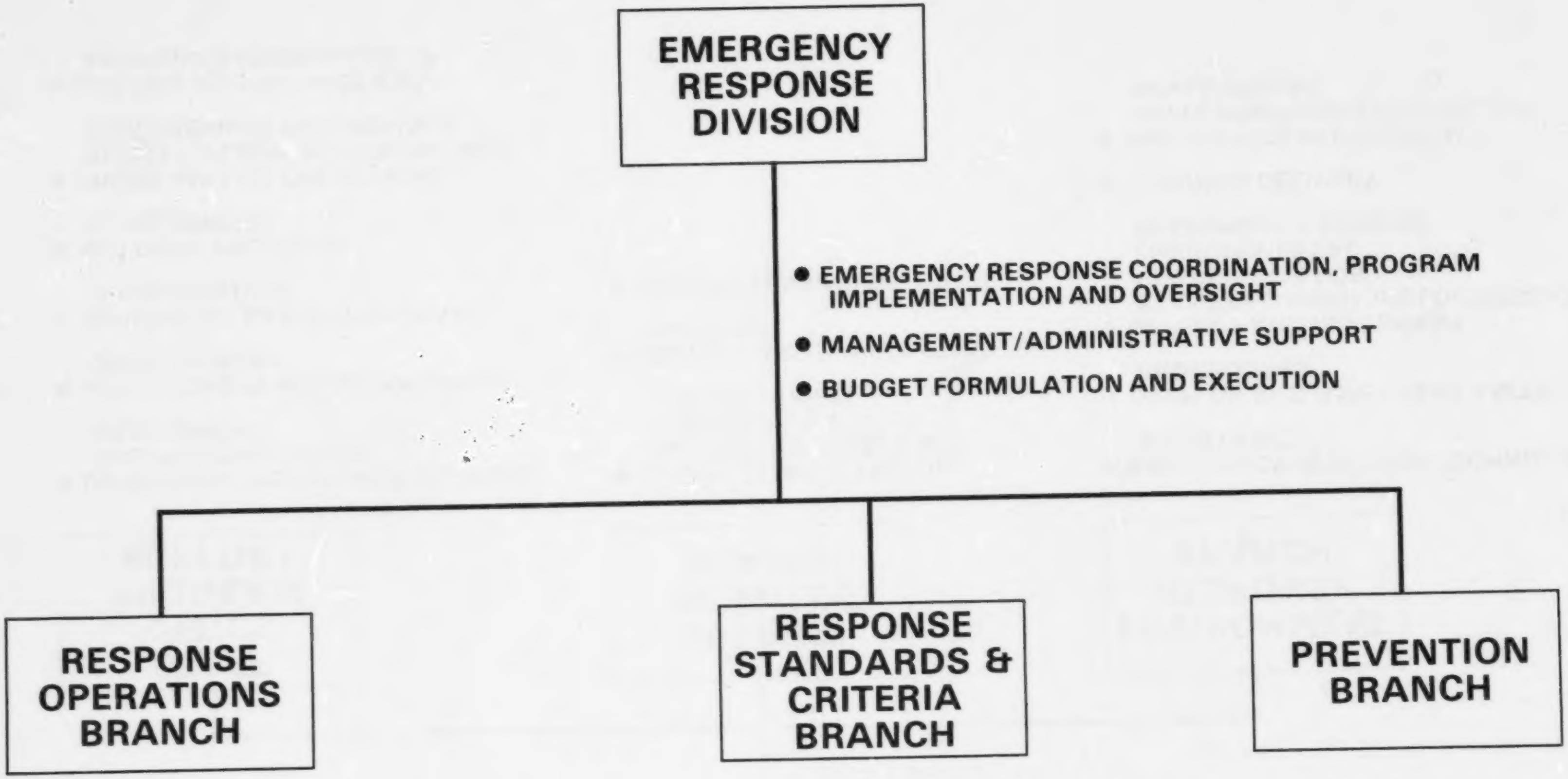
- NATIONAL CONTINGENCY PLAN SUPPORT
- REGULATION DEVELOPMENT AND COORDINATION
- COMMUNITY RELATIONS POLICY DEVELOPMENT
- PUBLIC AND CONGRESSIONAL INQUIRIES/TESTIMONY
- SPECIAL STUDIES/TREASURY RCRA COORDINATION
- INTERAGENCY BUDGET

PROGRAM MANAGEMENT BRANCH

- ORGANIZATIONAL MANAGEMENT
- PROGRAM EVALUATION AND MANAGEMENT REPORTS
- OPERATING PLANS
- BUDGET EXECUTION
- FUND MANAGEMENT
- CLAIMS REGULATIONS
- GUIDANCE DEVELOPMENT AND COORDINATION
- DELEGATIONS OF AUTHORITY

DATA MANAGEMENT BRANCH

- ADP RESOURCE MANAGEMENT
- APPLICATION SYSTEMS DEVELOPMENT
- APPLICATION SYSTEM OPERATION
- APPLICATION SYSTEM EVALUATION
- TECHNICAL SUPPORT/LIAISON



EMERGENCY RESPONSE DIVISION

- EMERGENCY RESPONSE COORDINATION, PROGRAM IMPLEMENTATION AND OVERSIGHT
- MANAGEMENT/ADMINISTRATIVE SUPPORT
- BUDGET FORMULATION AND EXECUTION

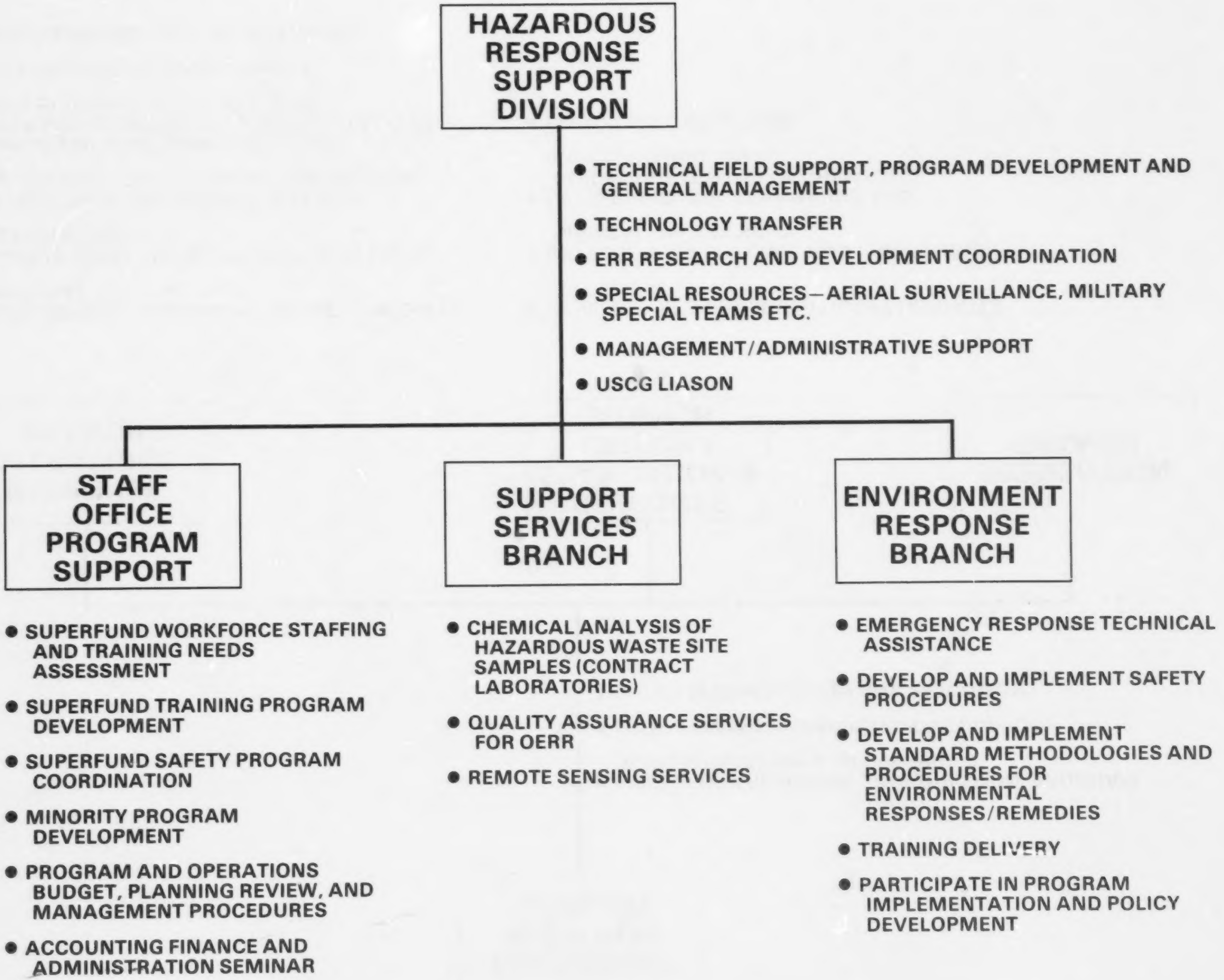
RESPONSE OPERATIONS BRANCH

- MANAGEMENT AND OVERSIGHT OF IMMEDIATE REMOVAL ACTIONS
- MANAGEMENT AND OVERSIGHT OF PLANNED REMOVAL ACTIONS
- DEVELOPMENT OF OPERATIONAL AND ADMINISTRATIVE GUIDANCE FOR REGIONS
- MANAGEMENT OF CONTRACTS FOR OPERATIONS SUPPORT TO REGION (TAT AND CLEANUP SERVICES CONTRACTS)
- STATE PROGRAM DEVELOPMENT
- OHM/TADS AND SPCC MAINTENANCE

RESPONSE STANDARDS & CRITERIA BRANCH

- DEVELOPMENT OF REGULATIONS MANDATED BY CERCLA
- DEVELOPMENT OF PLANS AND PROCEDURES MANDATED BY CERCLA
- DEVELOPMENT OF STANDARDS AND GUIDELINES FOR USE OF CHEMICAL COUNTERMEASURES
- COMMUNITY RELATIONS

PREVENTION BRANCH



HAZARDOUS RESPONSE SUPPORT DIVISION

- TECHNICAL FIELD SUPPORT, PROGRAM DEVELOPMENT AND GENERAL MANAGEMENT
- TECHNOLOGY TRANSFER
- ERR RESEARCH AND DEVELOPMENT COORDINATION
- SPECIAL RESOURCES—AERIAL SURVEILLANCE, MILITARY SPECIAL TEAMS ETC.
- MANAGEMENT/ADMINISTRATIVE SUPPORT
- USCG LIASON

STAFF OFFICE PROGRAM SUPPORT

- SUPERFUND WORKFORCE STAFFING AND TRAINING NEEDS ASSESSMENT
- SUPERFUND TRAINING PROGRAM DEVELOPMENT
- SUPERFUND SAFETY PROGRAM COORDINATION
- MINORITY PROGRAM DEVELOPMENT
- PROGRAM AND OPERATIONS BUDGET, PLANNING REVIEW, AND MANAGEMENT PROCEDURES
- ACCOUNTING FINANCE AND ADMINISTRATION SEMINAR

SUPPORT SERVICES BRANCH

- CHEMICAL ANALYSIS OF HAZARDOUS WASTE SITE SAMPLES (CONTRACT LABORATORIES)
- QUALITY ASSURANCE SERVICES FOR OERR
- REMOTE SENSING SERVICES

ENVIRONMENT RESPONSE BRANCH

- EMERGENCY RESPONSE TECHNICAL ASSISTANCE
- DEVELOP AND IMPLEMENT SAFETY PROCEDURES
- DEVELOP AND IMPLEMENT STANDARD METHODOLOGIES AND PROCEDURES FOR ENVIRONMENTAL RESPONSES/REMEDIES
- TRAINING DELIVERY
- PARTICIPATE IN PROGRAM IMPLEMENTATION AND POLICY DEVELOPMENT

HAZARDOUS SITE CONTROL DIVISION

- REMEDIAL RESPONSE COORDINATION AND OVERSIGHT
- COMMUNITY RELATIONS
- HAZARDOUS SITE INFORMATION AND TECHNOLOGY TRANSFER PROCEDURES FOR ENVIRONMENTAL RESPONSES/REMEDIES
- MANAGEMENT/ADMINISTRATIVE SUPPORT

DISCOVERY & INVESTIGATION BRANCH

- HAZARDOUS SITE INVENTORY AND INVESTIGATION
- NATIONAL PRIORITIES LIST
- FIELD INVESTIGATION TEAM (FIT) CONTRACT

REMEDIAL ACTION BRANCH

- REMEDIAL RESPONSE POLICY DEVELOPMENT
- DETERMINE EXTENT OF RESPONSE AND COST EFFECTIVENESS METHODOLOGY
- REMEDIAL RESPONSE PLANNING AND IMPLEMENTATION
- REMEDIAL RESPONSE MANAGEMENT CONTRACTS
- MANAGE U.S. ARMY CORPS OF ENGINEERS AGREEMENT

STATE AND REGIONAL COORDIN. BRANCH

- ACTION MEMOS ALLOCATING REMEDIAL FUNDS
- COOPERATIVE AGREEMENTS WITH STATES
- SUPERFUND STATE CONTRACTS
- REGIONAL/STATE GUIDANCE AND TECHNICAL ASSISTANCE
- MANAGEMENT AND OVERSIGHT OF MITRE CONTRACT
- ESTABLISH INTRA-AGENCY PROCEDURES

STATUTORY AUTHORITIES

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980

Public Law 96-510   42 U.S.C. § 9601

The Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), Public Law 96-510, authorizes the Federal government to respond directly to releases or threatened releases of hazardous substances, pollutants or contaminants that may endanger the public welfare. Until this law was passed, the Federal government lacked the general authority to clean up hazardous wastes sites or respond to spills of hazardous substances onto land or into the air or non-navigable waters. While the Congress had addressed hazardous wastes problems before (RCRA), Federal responsibilities were mostly regulatory.

Key Sections of Act -- Toxics Focus

sec. 101(14), 102, 104	Covers "hazardous substances" releases into the "environment." Oil is specifically excluded. "Hazardous substances" defined as those substances designated or regulated under specified sections of other statutes, including the Toxic Substances Control Act, the Clear Air Act, the Clean Water Act and the Resource Conservation and Recovery Act (RCRA), and substances designated under section 102 of CERCLA.
sec. 102, 103	Administrator is required to designate spectific amounts of hazardous substances to be "reportable quantities" -- that amount of a substance which, when released, "may present substantial danger" to public health or welfare or the environment. Due to this requirement, close coordination must be maintained between CERCLA, CWA, CAA and TSCA. Certain persons in charge of vessels or facilities are required to report to the National Response Center the release of a reportable quantity of a hazardous substance.

sec. 101 (23), & (24), 104	Authorizes two kinds of direct government response to releases of hazardous substances or certain pollutants or contaminants into the environment: - Removal Action is taken to mitigate an immediate danger and ordinarily is limited to six months in duration and $1 million in cost. - Remedial Action is taken when more permanent remedy is necessary. States must make certain assurances including sharing at least 10 percent of response costs or at least 50 percent if the facility from which release occurs was owned by state or local government.
sec. 104(i)	Requires establishment of the Agency for Toxic Substances and Disease Registry in HHS. Requires this Agency to effect the health-related provisions of the Act, including, among others, establishing a registry of persons exposed to hazardous substances and medical testing and evaluation of exposed individuals.
sec. 105	NCP establishes procedures for carrying out removal and remedial actions and encourages coordinated federal, state and local involvement. NCP also includes a list of national priorities for remedial action. List must include at least 400 sites drawn from candidates submitted by the States.
sec. 106	Authorizes abatement action and issuance of orders to compel private cleanup or other measures when public health or environment is endangered. Establishes substantial fines for non-compliance.

sec. 107	Imposes liability for response costs incurred by federal government, state, or other persons and for damages or loss to natural resources. Potentially liable parties include owners/operators of vessels and facilities, owners/operators of disposal facilities, and generators and transporters of hazardous substances. Establishes narrow defenses to liability (an act of God, an act of war, or an act of omission by an unrelated third party).Creates limits to liability.
sec. 111	Authorizes use of Superfund monies for payment of response costs and certain claims under the Clean Water Act and claims for natural resource damage.
sec. 112	Establishes procedures for paying claims authorized under section 111. Authorizes President to assist in settlement and requires the establishment of a Board of Arbitrators to decide claims.
Title II	Establishes the Hazardous Substance Response Trust Fund which is financed primarily by a five-year tax on crude oiland certain petroleum products and on the sale of certain chemicals by manufacturers, producers, or importers. Creates the Post-Closure Liability Trust Fund, financed by a tax on the receipt of hazardous wastes at disposal facilities, to cover liability for property closed facilities.
sec. 301	Requires the President to submit to Congress comprehensive reports on CERCLA's implementation. Reports concern the effectiveness of CERCLA for responding to hazardous substance releases, a summary of disbursements from the Fund a record of state participation, and the impact of taxes imposed by Title II on the nation's trade balance.

The Clean Water Act

Public Law 95-676 33 U.S.C. § 1321

The Clean Water Act and its predecessor, the Federal Water Pollution Control Act, enabled the Federal Government to take action when oil or designated hazardous substances are discharged into navigable waters. This statute did not permit the Government to act when hazardous substances were released elsewhere into the environment. EPA's Superfund program, in close coordination with the U.S. Coast Guard, administers programs under section 311 of the Clean Water Act.

sec. 311 Jurisdiction: Oil and hazadous substance discharges "into the navigable waters of the United States, adjoining shorelines, or . . . the water of the contiguous zone."

Removal authorities: President authorized to remove oil or hazardous substances discharged into navigable waters.

Liability: Imposed for removal costs and restoration/replacement of natural resources. Defenses and limits to liability are established.

Enforcement: Civil penalties for violation of the Act; injunctive relief authorized (section 504(a)).

Fund: $35 million revolving fund established to finance removals and implementation of other section 311 authorities.

Existing Regulations and Policy Statements Mandated by the Comprehensive Environmental Response, Compenstation and Liability Act of 1980 or Section 311 of the Clean Water Act

The National Oil and Hazardous Substance Contingency Plan	40 CFR Part 300
Oil and Hazardous Substance Emergencies	40 CFR Parts 100-117

TOXICS RELATED ACTIVITIES

The following regulations are under development pursuant to CERCLA and section 311 of the Clean Water Act.

Designation of Hazardous Substances -- 40 CFR 302

Section 102 of CERCLA requires EPA to designate hazardous substances which may present substantial danger to the public health or welfare or the environment if released into the environment. EPA is developing this regulation to supplement the lists of hazardous substances already developed under CWA 307, 311, RCRA 3001, CAA 112, and TSCA 7.

Notification of Release of Hazardous Substances and Determination of Reportable Quantities -- 40 CFR 303

EPA is developing reportable quantities for hazardous substances under section 102 of CERCLA that will trigger the requirements in section 103 of CERCLA. The reportable quantity listed with each designated hazardous substance under CERCLA section 102 will be the reportable quantity for that substance under CWA section 117.3.

Notification of Continuous Release of Hazardous Substances -- 40 CFR 304

Section 103(a) of CERCLA requires that persons notify the National Response Center of releases of hazardous substances. Section 103(f) provides an exemption to these reporting requirements. EPA is developing regulations that will clarify Agency policy regarding notification of continuous releases of designated hazardous substances.

OFFICE OF AIR, NOISE, AND RADIATION

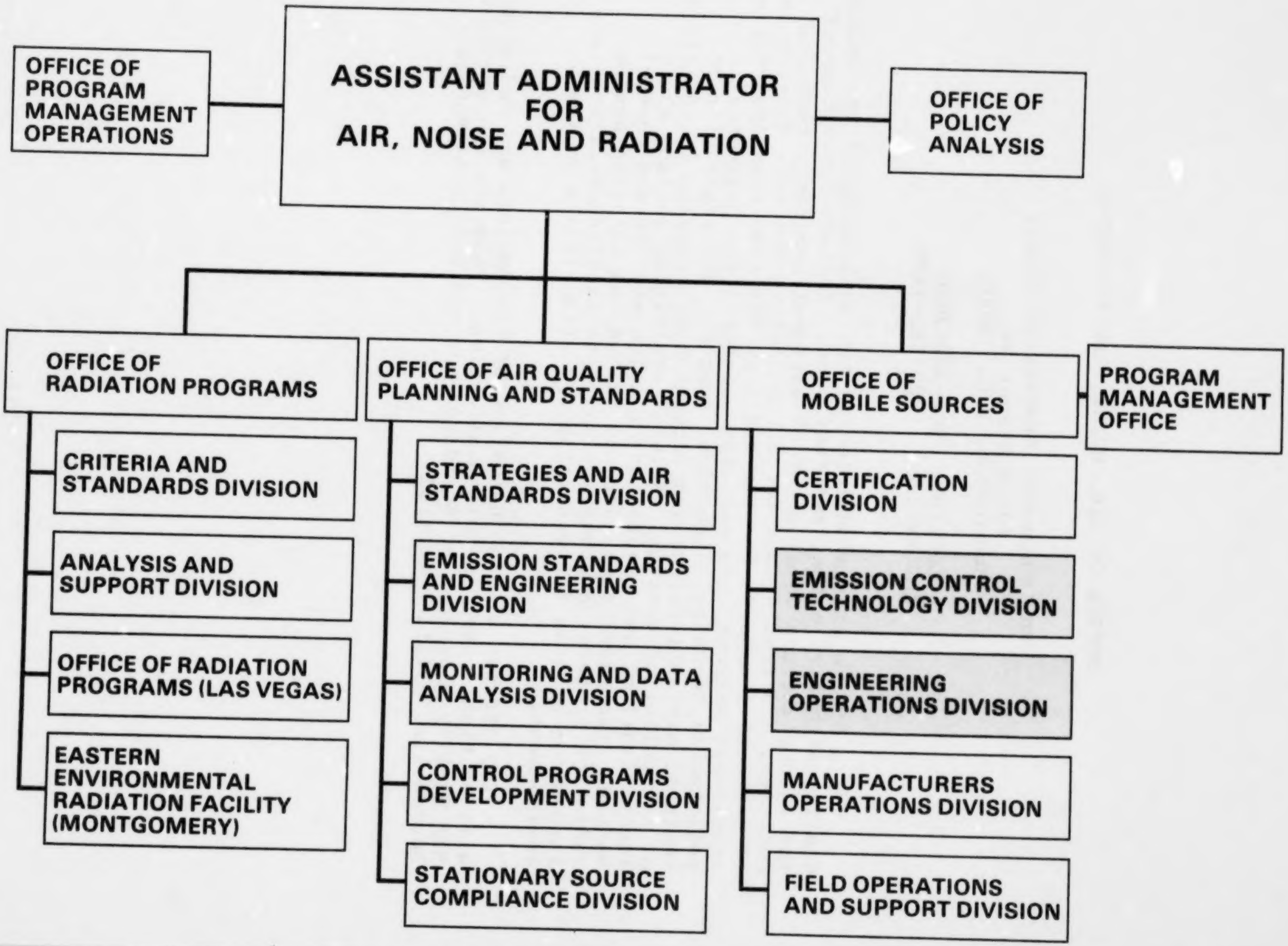
Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-7400

This Office is responsible for the activities of the Agency dealing with air, noise, and radiation. The air activities of the Agency include development of national programs, technical policies, and regulations for air pollution control; development of national standards for air quality, emission standards for new stationary sources, and emission standards for hazardous pollutants; technical direction, support, and evaluation of regional air activities; and provision of training in the field of air pollution control. Related activities include study, identification, and regulation of noise sources and control methods; technical assistance to States and agencies having radiation protection programs; and a national surveillance and inspection program for measuring radiation levels in the environment.

Two offices within the Office of Air, Noise, and Radiation will be highlighted in this publication. They are the Office of Air Quality Planning and Standards and the Office of Mobile Source Air Pollution Control.

OFFICE OF AIR, NOISE AND RADIATION


ASSISTANT ADMINISTRATOR FOR AIR, NOISE AND RADIATION
OFFICE OF PROGRAM MANAGEMENT OPERATIONS
OFFICE OF POLICY ANALYSIS
OFFICE OF RADIATION PROGRAMS
CRITERIA AND STANDARDS DIVISION
ANALYSIS AND SUPPORT DIVISION
OFFICE OF RADIATION PROGRAMS (LAS VEGAS)
EASTERN ENVIRONMENTAL RADIATION FACILITY (MONTGOMERY)
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
STRATEGIES AND AIR STANDARDS DIVISION
EMISSION STANDARDS AND ENGINEERING DIVISION
MONITORING AND DATA ANALYSIS DIVISION
CONTROL PROGRAMS DEVELOPMENT DIVISION
STATIONARY SOURCE COMPLIANCE DIVISION
OFFICE OF MOBILE SOURCES
PROGRAM MANAGEMENT OFFICE
CERTIFICATION DIVISION
EMISSION CONTROL TECHNOLOGY DIVISION
ENGINEERING OPERATIONS DIVISION
MANUFACTURERS OPERATIONS DIVISION
FIELD OPERATIONS AND SUPPORT DIVISION

OFFICE OF AIR QUALITY PLANNING AND STANDARDS

U.S. EPA (ANR-443)
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-5575

U.S. EPA (MD-11)
Research Triangle Park, NC 27711

Locator: 919-541-5615
8-629-5615

Information: 919-541-5615
8-629-5615

OFFICE OF MOBILE SOURCES

Environmental Protection Agency
401 M Street SW.
Washington, D.C. 20460

Locator: 202-382-2090
Information: 202-382-7645

Organization....................page 316
Statutory Authority.............page 320
Regulatory Development..........page 323
Toxics-Related Activities.......page 324

The Office of Air Quality Planning and Standards is responsible for the air quality planning and standards functions of the Agency. As such, this Office develops national standards for air quality, emission standards for new stationary sources, and emission standards for hazardous pollutants. In addition,

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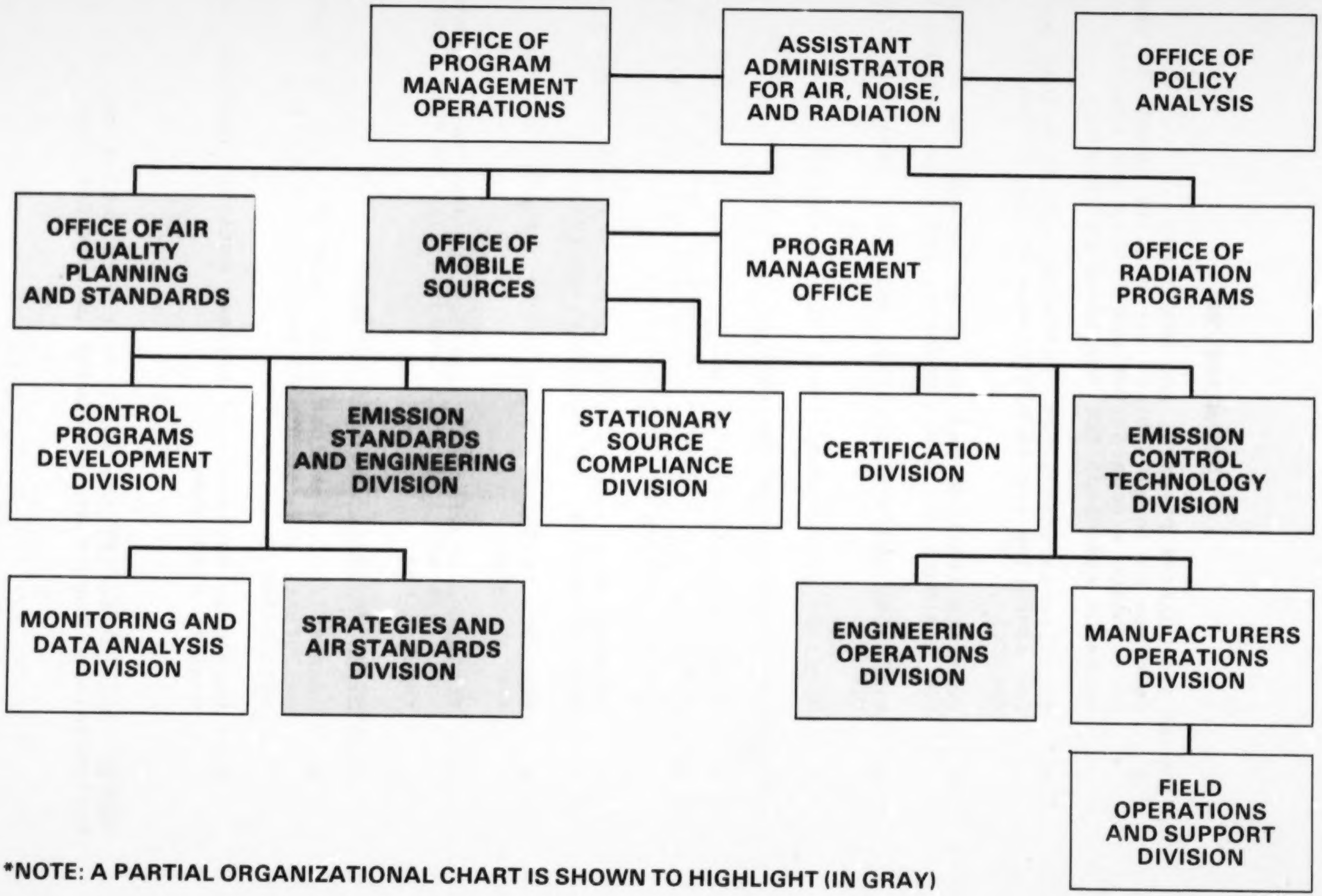
*NOTE: Since both of these Offices are responsible for implementing activities under The Clean Air Act, they are covered in the same section of this publication. This represents a slight change in format.

the Office develops national programs, technical policies, regulations, guidelines, and criteria for air pollution control; assesses the national air pollution control program; provides assistance to States and the Regional Offices, develops emission factors and monitoring strategies for toxic air pollutants and monitors compliance with stationary sources emissions limitations under the Clean Air Act.

The Office of Mobile Sources, under the supervision of a Director, is responsible for the mobile source air pollution control functions of the Office of Air, Noise and Radiation. The Office is responsible for characterizing emissions from mobile sources and related fuels; developing programs for their control, including assessment of the status of control technology and in use vehicle emissions; for carrying out, in coordination as appropriate with the Office of Legal and Enforcement Counsel, regulatory compliance programs to ensure adherence of mobile sources to standards; and for fostering the development of State motor vehicles.

ENVIRONMENTAL PROTECTION AGENCY*
OFFICE OF AIR, NOISE, AND RADIATION
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
OFFICE FOR MOBILE SOURCE AIR POLLUTION CONTROL


OFFICE OF PROGRAM MANAGEMENT OPERATIONS
ASSISTANT ADMINISTRATOR FOR AIR, NOISE, AND RADIATION
OFFICE OF POLICY ANALYSIS
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
OFFICE OF MOBILE SOURCES
PROGRAM MANAGEMENT OFFICE
OFFICE OF RADIATION PROGRAMS
CONTROL PROGRAMS DEVELOPMENT DIVISION
EMISSION STANDARDS AND ENGINEERING DIVISION
STATIONARY SOURCE COMPLIANCE DIVISION
CERTIFICATION DIVISION
EMISSION CONTROL TECHNOLOGY DIVISION
MONITORING AND DATA ANALYSIS DIVISION
STRATEGIES AND AIR STANDARDS DIVISION
ENGINEERING OPERATIONS DIVISION
MANUFACTURERS OPERATIONS DIVISION
FIELD OPERATIONS AND SUPPORT DIVISION

*NOTE: A PARTIAL ORGANIZATIONAL CHART IS SHOWN TO HIGHLIGHT (IN GRAY)

ORGANIZATION*

OFFICE OF AIR QUALITY PLANNING AND STANDARDS

- Develops national ambient air quality standards and performance standards for new stationary sources and emission standards for hazardous pollutants.
- Establishes guidelines, criteria, and technical policies for assessing the effectiveness of air pollution controls.
- Provides training and technical information to States, EPA Regional Offices, industry, and other organizations.
- Evaluates regional programs and State implementation plans.
- Monitors source compliance with standards.

Emission Standards and Engineering Division

- Develops reviews, and revises national emission standards for hazardous pollutants and performance standards for new stationary sources. Provides guidance for delegation of standards.
- Studies stationary source categories and analyzes control methods and economic information.
- Provides technical expertise in emission control technologies.
- Evaluates development alternatives for their technical soundness and for their compatibility to emissions regulations.

Strategies and Air Standards Division

- Identifies and evaluates the need to regulate potential pollutants and recommends appropriate control strategies.
- Develops, reviews, and revises national ambient air quality standards.

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*NOTE: Only those offices which deal with toxics or toxics-related issues are developed in this section.

- Prepares cost, economic, and benefit analysis in support of regulatory actions.

Monitoring and Data Analysis Division

- Develops emission factors for toxic air pollutants.
- Develops strategy for monitoring toxic air pollutants.

OFFICE OF MOBILE SOURCES

- Characterizes emissions from mobile sources and develops control programs.
- Recommends emission standards and any related test procedures for mobile sources.
- Conducts regulatory compliance programs to ensure that mobile sources adhere to the standards developed.

Emission Control Technology Division

- The Emission Control Technology Division, under the supervision of a Director, is responsible for assessing emissions from all mobile sources and developing new emission standards in cases where the new standards are effective to implement. To support the goal of standards development, the Division must consider test procedure development, technology assessments, characterization of regulated and unregulated pollutants from currently regulated and nonregulated sources, cost effectiveness analyses, fuel economy test procedures and the relationships between fuel economy and emissions, in-use vehicle performance assessments and the feasibility of implementing in-use vehicle control strategies.

Engineering Operations Division

- The Engineering Operations Division (EOD), under the supervision of a Director, is responsible for the complete range of tasks required to provide the necessary facilities and equipment in support of all emission and fuel economy testing programs at the Ann Arbor facility; provides emission testing services in support of the Automobile Emission Certification Testing Program and the Fuel Economy Testing Program and other compliance programs; conducts correlation activities with other governmental and industry emission test facilities on a nationwide and international basis in the form of evaluation and diagnostic testing and technical consultation; conducts audits of manufacturers' test facilities to determine the acceptability of their procedures (and, ultimately, their data) for purposes of certification program and fuel economy program implementation; conducts testing for other EPA and OMS organizations of a specialized nature in support of emerging issue assessments, emerging problem areas, or specialized compliance activities.

DIRECTORY FOR TOXICS-RELATED OFFICES AND PERSONNEL

Division/Office	Phone	Mail Stop
* Office of Air Quality Planning and Standards	202-382-5575 and 919-541-5615 8-629-5615	ANR-443 401 M Street SW. Washington, D.C. 20460 MD-11 Research Triangle Park, NC 27711
Emission Standards and Engineering Division	919-541-5571 8-629-5571	MD-13 Research Triangle Park, NC 27711
Strategies and Air Standards Division	919-541-5504 8-629-5204	MD-12 Research Triangle Park, NC 27711
Monitoring and Data Analysis Division	919-541-5536 8-629-5536	MD-14 Research Triangle Park, NC 27711
Stationary Source Compliance Division	202-382-2807 8-382-2807	EN 341 401 M Street SW. Washington, D.C. 20460
Office of Mobile Sources	202-382-7645 8-382-7645	ANR-455 401 M Street SW. Washington, D.C. 20460
Emission Control Technology Division	313-668-8404 8-374-8404	2565 Plymouth Road Ann Arbor, MI 48105
Engineering Operations Division	313-668-8243 8-374-8243	2565 Plymouth Road Ann Arbor, MI 48105

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*Note that the Director, OAQPS and the Stationary Source Compliance Division are located in Washington, D.C. The other divisions are at the RTP address.

STATUTORY AUTHORITY

Clean Air Act
Public Law 95-11 42 U.S.C. § 7401 et seq.

The Federal mandates for reducing air pollution and improving air quality are embodied in legislation originally passed in 1955 and strengthened in 1963, 1965, and 1967. Comprehensive national control legislation came with the 1970 and 1977 amendments to the Clean Air Act.

1970 Amendments

Before 1970, the Act provided for national control of motor vehicle emissions studies as well as nationwide planning of possible control methods, and empowered States to set pollution control goals.

The 1970 amendments required the Federal Government to set standards for ambient air quality. These standards were to define the principal types of pollution and the levels of each that should not be exceeded for the protection of public health and welfare. EPA formally adopted the first ambient air quality standards in 1971. These amendments also specified emission standards for automobiles.

1977 Amendments

In the late 1960s, study and planning efforts had been based on individual air quality regions on the presumption that air pollution problems (and their solutions) would vary from place to place throughout the country. An air quality region was defined as an area with definite pollution problems, common pollution sources, and characteristic weather. Though the geographical boundaries were seldom exact, the air quality regions were useful units for management and control; each region had individual problems and individual characteristics.

The regional concept is still in use in the planning and control measures being carried out by EPA and the various states, and the 1977 amendments require the States to rate each region for its attainment of each air quality standard.

In addition, Congress strengthened efforts to maintain air quality in regions where the air is already clean. There cannot be any "significant deterioration" of air quality in such regions. The law specifies how sulfur oxides and particulates will first be regulated in "clean-air regions," and anticipates later regulation of other pollutants.

Three kinds of "clean-air regions" are defined. Class I must include all national parks and wilderness areas and may include further areas named by the States to remain unsullied. Class II areas can have some industrial development, up to specified levels. Class III areas can have greater pollution from additional new sources, sometimes up to the minimum Federal Ambient Standards.

Any significant pollution source--factory, power plant, or other--that is proposed must first obtain a permit and meet a number of conditions, which include using the best available control methods for the new source.

Industrial development is also permitted in polluted regions as long as offsetting reductions are made in that region's existing sources. A new tire factory, for instance, although it meets the new source performance standards for the rubber industry, would still add more pollution to the region. Under the new amendments, the factory can be built if existing sources reduce their emissions more than enough to compensate for the new plant.

Key Sections of Act--Toxics Focus

sec. 108	Authorizes EPA to establish air quality criteria and control techniques for air pollutants from both stationary and mobile sources.
sec. 109	Gives EPA authority to prescribe national ambient air quality standards.
sec. 110	Establishes State implementation plans for attainment of air quality standards.
sec. 111	Authorizes the establishment of standards for performance of new stationary sources of air pollutants; requires State plans for implementing control of existing plants in source categories covered by NSPS.
sec. 112	Defines hazardous air pollutants and authorizes the establishment of emission standards for such pollutants; authorizes EPA to impose alternative controls when emission standards are not feasible.

sec. 202	Authorizes motor vehicle emission standards and in some cases, sets the standards.
sec. 211	Requires registration of fuel and fuel additives. Authorizes control or prohibition of fuels and fuel additives. Prohibits marketing of new fuels or additives without a waiver.
sec. 303	Gives EPA emergency powers to act to stop air pollution emissions if necessary to protect against imminent dangers to health.

Regulatory Options Available Under Statute

- Designation of criteria pollutants and establishment of ambient air quality standards
- Imposition of new source performance standards and subsequent state standards on a category of emitter--can entail numerical limit or engineering control
- Listing as a hazardous air pollutant on health grounds and imposition of controls on significant emitters--as a numerical standard or engineering control
- Use of emergency powers in case of imminent hazard--litigation for RO/TRO.

REGULATORY DEVELOPMENT

REGULATORY PROCESS

For a discussion of the regulatory process within EPA, see page 233 of this publication.

EXISTING REGULATIONS

CLEAN AIR ACT	40 CFR 50-87

TOXICS-RELATED ACTIVITIES*

New Source Performance Standards

New Source Performance Standards are specific limits applicable to individual industries. They set the maximum amounts of each kind of pollutant, such as sulfur dioxide or particulates that can be emitted from new plant smokestacks for each unit of the plant's production. Standards of performance are proposed following a detailed investigation of air pollution control methods available to the industry and the impact of their cost to the industry. The investigations are conducted to ensure that standards: (1) realistically reflect best demonstrated control practices; (2) adequately consider the cost, nonair quality health and environmental impacts, and energy requirements of such control; (3) are applicable to existing sources that are modified or reconstructed as well as new installations; and (4) meet these conditions for all variations of operating conditions being considered anywhere in the country. Nationwide standards for new sources are intended to discourage new industrial plants from locating in States with less stringent regulations. Under the Federal standards, the industry would have to build a new plant in compliance with the new source performance standards. For pollutants not covered by a national ambient standard or a hazardous emission standard, the NSPS provisions of the Act require states to adopt standards for control of emissions of that pollutant from existing plants.

National Emission Standards for Hazardous Pollutants

Under the authority of section 112(b)(1) of the Clean Air Act, EPA may propose national emission standards for specific air pollutants that are particularly hazardous to health. Standards are set, at a minimum, to require the best available technology for both new and existing sources of the pollutant and to limit the amounts which owners and operators of plants emitting the pollutant may discharge into the atmosphere. To arrive at the proposed limits, EPA considers economic, environmental, and energy impacts associated with both the proposed standard, and its alternatives.

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*Included are those activities identified as toxics-related from the information provided by each agency at the time of publication. It is recognized that some activities may have been inadvertently omitted. Please bring any such omissions or new additions to the attention of the Office of Pesticides and Toxic Substances, Toxics Integration staff.

Motor Vehicle Emission Laboratory

The Motor Vehicle Emission Laboratory (MVEL) is staffed by three Divisions and numerous support groups. They are responsible for characterizing motor vehicle emissions, assessing new technology, developing test procedures, developing regulations and helping establish emission inspection and maintenance programs.

PROGRAMS

NATIONAL TOXICOLOGY PROGRAM

Department of Health and
Human Services
Public Health Service
P.O. Box 12233
Research Triangle Park, N.C. 27709

Information: 919-541-3991

Organization...................page 331
Statutory Authorities..........page 340

The National Toxicology Program (NTP), established in November 1978 as a Department of Health and Human Services (DHHS) cooperative effort, coordinates and manages the Department's activities in toxicology testing and test development and validation. The four DHHS agencies whose relevant toxicology programs comprise the NTP are the National Cancer Institute*, National Institutes of Health (NCI/NIH); National Institute of Environmental Health Sciences (NIEHS/NIH); National Center for Toxicological Research, Food and Drug Administration (NCTR/FDA); and National Institute for Occupational Safety and Health, Centers for Disease Control.

NTP's goal is to develop the scientific information necessary to strengthen the science base in toxicology and to protect the health of the American public from exposure to toxic chemicals. Under the broad objective of identifying those chemicals potentially toxic to humans and developing and validating new and better integrated test methods, the NTP emphasizes four specific goals:

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*NOTE: On July 14, 1981, the DHHS Secretary approved the transfer of the NCI carcinogenesis bioassay program to the NIEHS in order to integrate the NIH components of the NTP. NIEHS is responsible for all NIH/NTP activities; but the NCI continues to be involved in the NTP through the Executive Committee, the Board of Scientific Counselors, and the operational components.

- To expand the spectrum of toxicologic information on chemicals being tested.

- To increase the numbers of chemicals tested in various short-term assays within funding limits.

- To develop and validate a series of test protocols more appropriate for regulatory needs.

- To establish a coordinated communications network to collect, evaluate, and disseminate toxicological information generated by the program.

The NTP's predominant long-term objective is the development, validation, and application of better, less expensive, more specific test methodologies. However, chemical testing for toxicology continues to be a central concern and to use the greatest amount of resources. By broadening the protocols to more fully characterize the overall toxicological profile of chemicals, the NTP has implemented a comprehensive approach to testing, one which examines the carcinogenicity, genetic toxicity, chemical disposition (absorption, distribution, metabolism, and excretion), fertility and reproductive effects, and major organ toxicity of chemicals.

To ensure that the NTP toxicology research, chemical testing priorities, and test development efforts are responsive to public health concerns and to regulatory needs, the NTP Executive Committee provides coordination between DHHS research and regulatory agencies. This committee, made up of the heads of the Federal research and regulatory agencies, serves as NTP's major advisory body and provides primary oversight for the program. This interagency group also serves as a forum for discussion of science policy issues and provides for timely information exchange among the various agencies as well as with industry and other interested groups.

Another responsibility of the Executive Committee has been the development of chemical nomination and selection procedures to determine which chemicals to examine toxicologically under the NTP activity. To ensure that its chemical selection takes into account both public and private concerns, the NTP urges all persons interested in proposing chemicals for testing to do so as well as recommend the type tests to be considered. Testing recommendations or questions should be directed to Dr. Dorothy Canter, NIH/NTP, Room 2B55, Bldg. 31, National Institutes of Health, Bethesda, MD 20205, (301) 496-3511 or FTS 629-3511.

In selecting chemicals for test, the NTP Executive Committee operates under the principle that industry will test chemicals for health and environmental effects as intended and mandated by the Congress under legislative authorities. Therefore, the NTP, acting under its chemical selection principles, will test:

1. Chemicals found in the environment that are not closely associated with commercial activities.

2. Desirable substitutes for existing chemicals, particularly therapeutic agents, that might not be developed or tested without Federal involvement.

3. Chemicals that should be tested to improve scientific understanding of structure-activity relationships and thereby assist in defining groups of commercial chemicals that should be tested by industry.

4. Certain chemicals tested by industry, or by others, the additional testing of which by the Federal Government is justified to verify the results.

5. Previously tested chemicals for which other testing is desirable to cross-compare testing methods.

6. "Old chemicals" with the potential for significant human exposure which are of social importance but which generate too little revenue to support an adequate testing program (some of these may be "grandfathered" under FDA laws).

7. Two or more chemicals together, when combined human exposure occurs (such testing probably cannot be required of industry if the products of different companies are involved).

8. In special situations, as determined by the Executive Committee, marketed chemicals which have potential for large-scale and/or intense human exposure, even if it may be possible to require industry to perform the testing.

The NTP Board of Scientific Counselors provides scientific oversight of the NTP, advises the Director and Executive Committee on scientific content and policy, and evaluates the quality of the research and testing conducted by the NTP components. When projects are completed and technical reports on the results are prepared, the Technical Reports Review Subcommittee of the Board, supplemented by an _ad hoc_ panel of expert reviewers, evaluates the reports for technical and scientific merit. Through this extensive review, the NTP is assured that its program efforts are of high quality and relevance.

To disseminate the information developed by the program, the NTP publishes a number of documents.*

- NTP Annual Plan - contains current information on plans for research, testing, and validation efforts and results from completed research.
- NTP Review of Current DHHS, DOE, and EPA Research Related to Toxicology - contains information on toxicological research and test methods development activities, as well as personnel and resources committed to those activities, at 17 DHHS agencies, DOE, and EPA.
- NTP Technical Bulletin - provides timely and frequent announcements of the NTP research activities and specific actions.
- Annual Report on Carcinogens - contains a listing of substances either "known" or "reasonably anticipated" to be carcinogens, as well as available information on the production and use of these substances, human exposures, and regulations designed to protect the public health.
- Technical Reports - provides results of NTP's long-term carcinogenesis studies. Reports for chemicals now being started on test will contain results related to target organ effects, chemical disposition, fertility and reproductive effects, urinalysis, clinical chemistry, hematology, and other endpoints as appropriate.

Through this testing and information dissemination, the NTP attempts to identify and provide information on hazardous chemicals so that preventive and protective measures can be taken to protect the health of the American public.

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*NOTE: To receive copies of or to be placed on the mailing list for any of the NTP publications, please write to: NTP Public Information Officer, P.O. Box 12233 (M.D. B2-04), Research Triangle Park, N.C. 27709, (919) 541-3991 or FTS 629-3991.

ORGANIZATION*

NIEHS/TOXICOLOGY RESEARCH AND TESTING PROGRAMS

- Plans and conducts research to develop, validate, and evaluate methods for characterizing the toxicology of chemical compounds and other environmental agents.
- Plans and conducts a program of research and testing, including short-term screening and long-term animal toxicology and carcinogenesis studies, to establish the toxicity of chemical compounds and other environmental agents.
- Collaborates with chemical toxicology test development and test programs of other government agencies.
- Disseminates results of tests, test development, and test validation efforts to interested members of the scientific community and to Federal regulatory agencies.

Carcinogenesis and Toxicology Evaluation Branch

- Designs, conducts, and interprets carcinogenesis and related studies on chemicals.
- Work closely with other branches to develop data that elucidate general mechanisms that may be involved in toxic effects.

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*The majority of NTP's budget and other resources are administered by the NTP Director, Deputy Director, and staff located within the NIEHS. The NIOSH and NCTR components are not under direct NTP management, but each plays a specific role in the program's operations, contributes on the basis of annual aggrements, and actively participates in the chemical selection process and on the Steering Committee. In these organizational sections, only those offices that are assigned specific responsibility for NTP activities and that deal with toxics or toxics-related issues are developed. However, other offices within these agencies may collaborate on NTP projects and carry out NTP-related activities.

- Conducts research intended to develop and validate improved toxicity testing methodologies, establish short-term and screening test systems, and improve interpretation of long-term toxicology and carcinogenesis results.

- Monitors testing program to assure the quality and validity of the toxicology components of the tests.

Systemic Toxicology Branch

- Develops methods for assessing toxic effects involving immune, renal, pulmonary, reproductive, and other bodily functions.

- Performs studies to develop basic knowledge of chemical absorption, distribution, metabolism, and excretion.

- Conducts research to improve test protocols, to develop new tests, and to improve interpretation of test results related to the toxicity of chemicals on a variety of organs, tissues, and cells.

- Collaborates as specific experts in fields such as toxicology, immunology, pharmacokinetics, and physiology with other scientific staff of the program involved in test development and validation and with test protocol preparation.

Cellular and Genetic Toxicology Branch

- Develops and validates a variety of *in vivo* and *in vitro* methods to detect and define effects of chemicals on genetic components.

- Develops and standardizes *in vivo* test systems as models for carcinogenesis and mutagenesis that provide for extrapolation to humans.

- Investigates somatic as well as heritable gene damage that results from exposure to environmental agents.

- Studies effects of chemicals on experimental organisms and on human populations.

- Develops and utilizes computer data files for storage, retrieval, and analysis of genetic toxicity test data.

Chemical Pathology Branch

- Provides pathology support to all segments of the NTP, and especially to carcinogenesis studies.
- Develops standards for tumor and non-tumor pathology diagnoses and nomenclature.
- Develops clinical chemistry parameters for assessing cellular and organ function.
- Monitors the testing program to assure the quality and validity of pathology components of the tests.

Program Operations Branch

- Maintains continual planning, oversight, coordination, and surveillance of toxicology testing activities.
- Undertakes scientific and technical monitoring of test laboratories.
- Provides logistical support for coordinating and scheduling the contract testing functions.
- Monitors quality assurance and good laboratory practices at the testing laboratories.

Program Resources Branch

- Provides a range of special support resources for toxicology and carcinogenesis testing and test development activities.
- Assures acquisition and quality control of test animals and provides for acquisition, quality control, and standardization of tests.
- Monitors laboratory safety, chemistry, and animal care practices.

NIOSH

- Protects U.S. workers from work-related hazards through a comprehensive research program designed to coordinate laboratory investigations, field surveys, and epidemiologic studies so the appropriate standards and controls can be developed.

- Concentrates research efforts to reduce unnecessary morbidity and mortality related to the ten leading work-related diseases and injuries:
  - Occupational lung diseases: asbestosis, byssinosis, silicosis, coal workers' pneumonconiosis, lung cancer, occupational asthma.
  - Musculoskeletal injuries: disorders of the back, trunk, upper extremity, neck, lower extremity; traumatically-induced Raynaud's phenomenon.
  - Occupational cancers (other than lung): leukemia; mesothelioma; cancers of the bladder, nose, and liver.
  - Amputations, fractures, eye loss, lacerations, and traumatic deaths.
  - Cardiovascular diseases: hypertension, coronary artery disease, acute myocardial infarction.
  - Disorders of reproduction: infertility, spontaneous abortion, teratogenesis.
  - Neurotoxic disorders: peripheral neuropathy, toxic encephalitis, psychosis, extreme personality changes (exposure-related).
  - Noise-induced loss of hearing.
  - Dermatologic conditions: dermatoses, burns (scalding), chemical burns, contusions (abrasions).
  - Psychologic disorders: neuroses, personality disorders, alcoholism, drug dependency.
- Develops criteria from research and evaluation studies for use by the Occupational Safety and Health Administration as the basis for its standards development process.

Division of Biomedical and Behaviorial Sciences

- Acts as lead division for NTP research.

- Conducts research in support of NTP on work-related diseases and injuries:

    - Occupational lung diseases: studies the etiology, dose-response, and interactive factors in occupationally-induced asthma.

    - Occupational cancers: performs bioassay screening of single chemicals; assesses carcinogenic potential of complex mixtures and the modification of carcinogenic action by promoters and cocarcinogens; studies the etiology of the carcinogenic process in various workplace environments; examines the influence of personal and occupational factors and substituted materials on the mechanisms of the diseases; studies the importance of the route of exposure.

    - Cardiovascular diseases: performs chronic inhalation studies to assess the potential toxic myocardial effects of selected aliphatic amines of industrial importance.

    - Disorders of reproduction: identifies and assesses chemicals that prevent or inhibit reproduction through effects on adults of either sex, interfere with normal development and produce effects either *in utero* or postnatally, and cause genetic disease and/or cancer through transplacental transfer.

    - Neurotoxic disorders: identifies and characterizes chemical hazards, reevaluates and develops recommended limits, and recommends substitute chemicals or improved work practices to reduce exposure.

    - Dermatologic conditions: develops and evaluates quantitative *in vivo* techniques for studying the extent and rate of percutaneous absorption of chemicals. These studies provide support for NTP skin carcinogenesis assays, such as with glutural-dehyde.

NCTR

- Determines adverse effects resulting from long-term, low-level exposure to various chemical substances.

- Develops experimental data to facilitate extrapolation of laboratory results to humans.

- Determines basic biological processes in animals to provide a more accurate extrapolation of laboratory results to humans.

- Develops improved methods and testing protocols for evaluating the relative safety of chemical substances.

Office of Scientific Intelligence

- Provides services to NCTR as a liaison and focal point on matters pertaining to the National Toxicology Program and the World Health Organization.

- Participates in compound nominations and selections for chemical evaluations for the NTP and prepares Executive Summaries on compound use, population exposure, and safety evaluations or research performed on selected compounds.

- Conducts chemical evaluations on selected NTP compounds.

Division of Mutagenesis Research

- Estimates the risk to humans from exposure to chemicals in the environment.

- Develops methods to measure both microlesions (single gene mutations or small deletions) and macrolesions (serious chromosomal aberrations) for use in toxicology and safety evaluations.

- Works to improve short-term, in vivo bioassays for identifying the effects of toxic substances on genes.

- Focuses research on developing reliable and economical methods for evaluating the genotoxic potential of chemicals. Results are then used to identify the chemical risk to humans.

Division of Teratogenesis Research

- Manages the teratology portion of the National Toxicology Program.

- Develops sound information bases of comparative pharmacokinetics and metabolism to define valid mathematical models for extrapolation of animal data to humans.

- Expands knowledge of basic developmental processes which can be affected by toxicants and defines mechanisms of teratogenicity.

- Develops and validates improved procedures for detecting the full range of possible toxic manifestations throughout the lifespan of the organism.

- Currently conducts four major projects: the Behavioral Teratology Collaborative Study, Reliability of Animal Models in Teratology, Development and Use of Mathematical Extrapolation Models in Teratogenesis, and Utility of Fetal Histopathology in Teratology Testing.

Division of Toxicology Data Management Systems

- Conceptualizes, develops, implements, and operates the Toxicology Data Management System (TDMS) at NCTR for the National Toxicology Program.

- Assists EPA Office of Testing and Evaluation in developing an automated data system, in accordance with TSCA guidelines.

NATIONAL TOXICOLOGY PROGRAM ORGANIZATIONAL AREAS AND LEADERS

MAJOR NATIONAL TOXICOLOGY PROGRAM AREAS AND LEADERS

Area	Leader	Contributing Agency*	Telephone	FTS
Director	Dr. D. P. Rall	NTP	919-541-3201	629-3201
Deputy Director	Dr. J. A. Moore	NTP	919-541-3267	629-3267
Toxicologic Research and Testing				
Carcinogenesis	Dr. R. Griesemer	NCI	202-496-5591	same
Short-Term Test Development	Vacant			
Tumor Pathology	Dr. J. Ward	NCI	202-496-6868	same
Chemical Disposition	Dr. H. Matthews	NIEHS	919-541-3369	629-3369
General Toxicology	Dr. J. Moore	NTP	919-541-3267	629-3267
Toxicopathology	Dr. E. McConnell	NIEHS	919-541-3231	629-3231
Genetic Toxicology	Dr. E. Zeiger	NIEHS	919-541-4482	629-4482
Immunologic Toxicology	Dr. J. Dean	NIEHS	919-541-4659	629-4659
Neurobehavioral Toxicology	Dr. C. Mitchell	NIEHS	919-541-3220	629-3220
Pulmonary Toxicology	Dr. T. Lewis	NIOSH	513-684-8392	same
Reproductive and Developmental Toxicology	Dr. J. Holson	NCTR	501-542-4303	same

MAJOR NATIONAL TOXICOLOGY PROGRAM AREAS AND LEADERS (cont.)

Area	Leader	Contributing Agency*	Telephone	FTS
Coordinative Management Activities				
Bioassay Coordination	Dr. J. F. Douglas	NCI	202-496-5591	same
Chemical Nomination	Dr. L. Fishbein	NCTR	501-542-4390	same
Chemical Repository	Dr. C. Jameson Dr. D. Walters	NCI NIEHS	202-496-1152 919-541-3355	same 629-3355
Data Management and Analysis	Dr. M. Hoel**	NIEHS	919-541-3205	629-3205
Carcinogenesis	Dr. K. Chu	NCI	202-496-1152	same
Mutagenesis	Dr. B. Margolin	NIEHS	919-541-3460	629-3460
Toxicology	Dr. J. Moseman	NIEHS	919-541-3437	629-3437
TDMS (Development)	Mr. A. Konvicka	NCTR	501-542-4534	629-4534
Information Dissemination	Dr. J. E. Huff	NTP	919-541-3780	629-3780
Laboratory Animal Quality Control	Vacant			
Laboratory Health and Safety	Dr. H. Maher	NCI	202-496-9526	same
Technical Information	Dr. H. Kissman	NLM	202-496-3147	same

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*Addresses: National Cancer Institute, Bethesda, MD 20205; National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709; National Library of Medicine, Bethesda, MD 20014; National Toxicology Program, Research Triangle Park, NC 27709; National Institute for Occupational Safety and Health, Cincinnati, OH 45226; National Center for Toxicological Research, Jefferson, AR 72079.

**Dr. J. Maseman, Acting Program Leader

NATIONAL TOXICOLOGY PROGRAM ORGANIZATIONAL AREAS AND LEADERS (con't.)

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STATUTORY AUTHORITY

Public Health Service Act
Public Law 78-410 42 U.S.C. § 201

The authority under which the NTP supports and conducts its activities in section 301 of the Public Health Service Act, which the Secretary of HHS broad powers to conduct and support research relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.

Key Sections of Act--Toxics Focus

sec. 301(a)	Authorizes Surgeon General to conduct and "promote the coordination of research investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams."
sec. 301(b)	Authorizes the Surgeon General to make available any research facilities, public authorities, health officials, or scientists engaged in related fields of study.

Public Law 95-622 42 U.S.C. § 241

Effective October 1, 1978, section 301 of the Public Health Services Act was amended to authorize the Secretary to conduct and support studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. This authority is in addition to that granted by the above sections.

Key Section of Act--Toxics Focus

sec. 301(b)(1)	Authorizes Secretary to conduct and support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

APPENDIX

STATUTORY AUTHORITIES TO CONTROL TOXIC SUBSTANCES IN TWELVE MAJOR ACTS

Prepared by

Hollis Call

The following charts are intended to provide a summary representation of the statutory authorities to control toxic substances and the major information gathering/producing authorities contained in 12 selected acts.

Limitations

These charts are designed to serve three essential purposes: one, to allow a quick reference of the statutory authorities contained in these 12 acts; two, to provide an overall picture of control authorities relevant to the lifecycle of a toxic substance; and three, to give an idea of some of the gaps, overlaps, and perhaps some of the legislative deficiencies present in the statutory framework for controlling toxic substances.

For each statute depicted in these charts, an appropriate Office or Agency administering that statute reviewed the material in an effort to make these charts as accurate as possible. However, for several reasons, there are some limitations on the use of this material.

First, this area of analysis is often very complex and further complicated by the fact that some of the statutory authorities shown in the charts have not yet been fully implemented or tested. Gernally, a complete interpretation of the statutes' authorities can be accomplished only by reviewing the respective statutes, the Code of Federal Regulations, and any administrative or judicial judgments affecting the way in which these authorities are interpreted and used.

Another limitation that should be pointed out arises as a consequence of attempting to subsume what are often broadly stated authorities into discrete categories. Thus, the fact that several sections of different statutes may be listed in one box does not necessarily indicate that these secitons can be equated. In most cases, they cannot. The additional analysis required to allow for direct comparison of these authorities is beyond the scope of this overview. However, a footnote is provided where the differences are particularly egregious. For convenience, only Chart 1 is footnoted; these footnotes apply as well to Charts 2 and 3.

Observations

There are several preliminary observations that might be made from a reading of these charts.

One is that although there may be specific instances of a lack of statutory authority to control a toxic hazard, there do not appear to be many gaping holes in the statutory framework. As TSCA becomes fully implemented the comprehensive coverage of the toxic substance lifecycle will increase.

However, the existence of a full complement of statutory authorities does not ensure or indicate effective control of toxic substances. Over 30 pieces of legislation have some regulatory authority over toxic substances. Each piece in this statutory framework was added incrementally over the past 2 decades. Each piece of legislation was a response to specific perceived needs and thus each has as a somewhat different orientation to toxic substance control, with different regulatory considerations.

The implications of these characteristics for regulating toxics, which typically fall under the jurisdiction of more than one statute, may be signficant. Deficiencies in the regulatory coverage may arise as a result of conflicts between shared jurisdictions and a lack of integrated operational relationships between Agencies rather than simply an absence of statutory coverage. Whether these relationships present themselves as obstacles or conversely as opportunities will in part help determine whether toxic substances are controlled effectively and efficiently.

On the vertical axis are eight different types of regulatory action that a statute might authorize to control toxics. These types, or classes, of control actions are general and are not intended to be exhaustive of all regulatory or control options available. In many instances, Agency efforts to control toxic substances are more subtle and indirect than the types of control actions listed in these charts. The Federal Insecticide, Fungicide, and Rodenticide Act's (FIFRA's) "rebuttable presumption against registration," for example, plays an important role in the regulatory fabric for regulating toxics, a role which is difficult to depict in these charts. Nevertheless, the types of control actions listed represent the predominant regulatory actions undertaken by Agencies to control toxic substances.

It should also be pointed out that there will be cases of overlap between these types of control actions. For example: a "guideline" or "standard" could be similar in effect to a "quantity limitation" or even a "prohibition," depending on how the standard was written and the response of the affected party. Distinctions between these authorities are based, in these charts, on a reading of the language in the statutes themselves.

The types of control actions listed in this chart should be self-descriptive. However, additional elaboration of the distinction between "labeling/packaging" and "notice" refers to the authority to require a specified party to give notice to those specifically exposed to a toxic hazard from a chemical substance or product which is in use, distribution, disposal, etc. "Labeling" authorities on the other hand, generally refer to requirements for labeling of products to reduce or eliminate the risk from a toxic chemical substance or product prior to potential exposure through distribution, use, transportation, or disposal.

Chart 1

The horizontal axis of this chart contains eight columns which represent eight "points" in the life cycle of a toxic substance. As such these points reflect both potential health or environmental exposure pathways, and potential points of regulatory control of a toxic substance.

Although the distinction made in these charts between manufacturing/processing, commerical distribution, transportation, use, etc., serves a useful analytical purpose, there may be overlap among these in some statutory provisions. Prohibiting or banning manufacturing/processing of a chemical, for example, would probably also have a similar effect on the end use of that chemical. On the other hand, a prohibition/ban on maufacturing of a chemical for a particular use would still allow manufacturing and use of that chemical for a particular use would still allow manufacturing and use of that chemical for non-banned uses. A decision by an Agency to control a toxic substance in either manufacturing, in use, or in manufacturing for a particular use, will depend largely upon the authorities available, the nature of the risk presented, and required regulatory considerations.

Charts 2 and 3

These charts contain the same information as Chart 1, but the information is referenced differently for user convenience. Chart 2 allows the reader to easily find any particular statute, control authorities. The lifecycle points to which each cited section of the statute apply are listed to the right of each section.

Chart 3 also allows referencing by statute, in this case according to points of lifecycle of a toxic substance. In this chart, the symbols representing the relevant control type are listed to the right of each section cited.

In both Charts 2 and 3, a legend appears at the bottom of the page referring to either types of control action (Chart 3) or chemical lifecycle (Chart 2).

Chart 4

Direct control actions taken by Agencies represented in these charts (Charts 1 thru 3) do not give a complete picture of the legislative framework to control toxic substances. Another significant class of authorities which complement control actions are provisions for gathering/producing information. Chart 4 contains selected information gathering/producing authorities in these 12 Acts. The information in this chart display was taken in part from an EPA publication, Chemical Reporting and Record-Keeping Authorities Under 15 Environmental and Consumer Acts.

CHART 1	MANUFACTURING/ PROCESSING	COMMERCIAL DISTRIBUTION	EMISSIONS, EFFLUENTS	TRANS-PORTATION	IMPORTS	END USE (PRODUCTS)	STORAGE/ DISPOSAL	WORKPLACE EXPOSURE
PROHIBITIONS/ BANS	TSCA 5(e), (f);[1] 6(a) CAA 211(c) CPSA 19(a)(1),(2)	TSCA 6(a)(1); 6(a)(2) CAA 211(c) CPSA 8; 19(a)(1),(2) FIFRA 6; 12(a); 13(a) FFDCA 301(a),(d) FHSA 4(a),(f)	CWA 307(a)(2) 306 311(b)(1)(B) SDWA 1424(a)	TSCA 6(a)(1);[4] 6(a)(2) CPSA 8; 19(a)[5] HMTA 105(a)	TSCA 13(a)(b) FIFRA 6; 12(a); 13(a) CPSA 17(a) FHSA 14(a) FFDCA 801(a)	CPSA 8 TSCA 6(a)(2)(A); 6(a)(5) FIFRA 6; 12(a); 13(a) FHSA 2(q)(1)(A)(B)	TSCA 6(a)(6) RCRA 3004, 3006	OSHA 13(a)[8]
QUANTITY LIMITATIONS	TSCA 5(f); 6(a)(2) CPSA 9(d)(2) CWA 301; 302; 304; 306	TSCA 6(a)(1); 6(a)(2)	CAA 110(a)(2)(B)[3] CWA 301 307(a)(2)	TSCA 6(a)(1); 6(a)(2) HMTA 106(a)[6]	TSCA 6(a)(5) CPSA 9(d)(2)	TSCA 6(a)(5)		
GUIDELINES, STANDARDS, QUALITY CRITERIA	TSCA 6(b)(2) CAA 111(b)(e) RCRA 3002(2),(3)		CWA 311(b)(1); 307(a)(2); 303;304;306 CAA 108;109; 111(a); 112(b)(1); 160-169; 202 SDWA 1421; 1412	FIFRA 19(b)[7] RCRA 3003 HMTA 106(a) CWA 311	TSCA 6(b)(2) CPSA 17(a)(1) FFDCA 801(a)	CAA 202(a)(1) CPSA 7(a)(1); 7(c) FIFRA 3(d) FFDCA 401;406;408 TSCA 6(a)(5)	CWA 307(a)(5) FIFRA 19 RCRA 3004, 3005 4004, 1008 TSCA (a)(6)	OSHA 5(a);6(a); 6(b)(5); 6(c)(1); 20(a)(2),(3); 22
REQUIRED LABELING/ PACKAGING PROVISIONS	TSCA 6(a)(3)[2]	TSCA 6(a)(3)		TSCA 6(a)(3) RCRA 3003(a)(2) HMTA 105(a)	TSCA 13(a) FIFRA 17(c) CPSA 17(a)(2) FHSA 14(a) FFDCA 801(a)	TSCA 6(a)(3) FIFRA 3(c)(5)(B) CPSA 7;14(c);27(c) FHSA 2(p);3(b) PPPA 3 FFDCA 505(d); 502;403;602; 512(d)(1)	TSCA 6(a)(3) RCRA 3002(2),(3) 3004	OSHA 6(b)(7)
REGISTRATION CERTIFICATION OR PERMITS	CPSA 14(a) CAA 165(a); 172(b) FIFRA 7(a) FFDCA 510	CAA 211(a);(b); 203(a)(1) FIFRA 3(a); 6 FFDCA 505; 512	CWA 301(b)(2); 401; 402 SDWA 1421; 1424(b)	• HMTA 106(b); 106(c) RCRA 3003	FIFRA 17(c) CPSA 17(a)(2)	FIFRA 3(a); 4(a); 5; 6; 18 CPSA 14(a) FFDCA 505 512 706 CAA 204; 211(b)	CWA 405 RCRA 3005	
RECALL, REPLACE, REPURCHASE, SEIZURE	TSCA 6(a)(7) CPSA 15(d) FHSA 15(a)(1)	CPSA 15(d),(c) FHSA 15(a)(2) FIFRA			FIFRA 13	TSCA 6(a)(7) FIFRA 12; 13 CPSA 15(d),(c) FHSA 6; 15(a) FFDCA 304		
TO REQUIRE NOTICE OF HAZARDS TO THOSE EXPOSED	TSCA 6(a)(7)		CWA 311(b)(2)			CPSA 15		OSHA 6(b)(7); 8(c)(3); 13(c); 20(a)(b)
IMMINENT HAZARDS	TSCA 7	CPSA 12 TSCA 7 FIFRA 6(c)	CWA 504 CAA 303; 311 RCRA 7003 SDWA 1431	TSCA 7 RCRA 7003 HMTA 111(b) CWA 311	TSCA 13(a) CPSA 17(a)(3) FHSA 14(a) FIFRA 6(c)	TSCA 7(a)(1) FIFRA 6(c) SDWA 1431(a) CPSA 12 FHSA 2(q)(2); 3(e)(2) FFDCA 505(e); 512(e)(1)	TSCA 7(a) RCRA 7003	OSHA 13

CHART 2	PROHIBITIONS/ BANS	QUANTITY LIMITATIONS	GUIDELINES, STANDARDS, QUALITY CRITERIA (MANNER OR METHOD)	REQUIRED LABELING/ PACKAGING	REGISTRATION CERTIFICATION, OR PERMITS	RECALL, REPLACE REPURCHASE, SEIZURE	TO REQUIRE NOTICE TO THOSE EXPOSED	IMMINENT HAZARDS
CAA	211(c) MP 211(c) CD	110(a)(2) EE	111(b),(e) MP 108 EE 109 EE 111(a) EE 112(b)(1) EE 160-169 EE 202 EE 202(a)(1) U		165(a) MP 172(b) MP 211(a),(b) CD 203(a)(1) CD 204 U 211(b) U			303 EE 311 EE
CWA	307(a)(2) EE 306 EE 311(b)(1) EE	301 MP 302 MP 304 MP 306 MP 301 EE 307(a) EE	303 EE 304 EE 306 EE 307(a)(2) EE 311(b)(1) EE 311 T 307(a)(5) D		301(b)(2) EE 401 EE 402 EE 405 D		311(b)(2) EE	504 EE 311 T
FIFRA	6;12(a);13(a) CD 6;12(a);13(a) I 17(c) I 6;12(a);13(a) U		19(b) T 3(d) U 19 D	17(c) I 3(c)(5) U	7(a) MP 3(a);(6) CD 17(c) I 3(a) U 4(a);5 U 6;18 U U	12 CD 13(a);(b) CD 12;13 U 13 I		6(c) CD 6(c) I 6(c) U
RCRA	3004 D 3005 D		3002 MP 3003 T 1008 D 3004 D 3005 D 4004 D	3003(a)(2) T 3002(2),(3) D 3004 D	3003 T 3005 D			7003 EE 7003 D
SDWA	1424(a) EE		1412 EE 1421 EE		1421 EE 1424(b) EE			1431 EE
TSCA	5(e),(f) MP 6(a) MP 6(a)(1) CD 6(a)(2) CD 6(a)(1) T 6(a)(2) T 13(a)(b) I 6(a)(2) U 6(a)(5) U 6(a)(6) D	5(f) MP 6(a)(2) MP 6(a)(1) CD 6(a)(2) CD 6(a)(1) T 6(a)(2) T 6(a)(5) I 6(a)(5) U	6(b)(2) MP 6(b)(2) J 6(a)(5) U 6(a)(6) D	6(a)(3) MP 6(a)(3) CD 6(a)(3) T 13(a) I 6(a)(3) U 6(a)(3) D		6(a)(7) MP 6(a)(7) U	6(a)(7) MP	7 MP 7 CD 7 T 13(a) I 7 U 7 D
CPSA	19(a) MP 8 CD 19(a) CD 8 T 19(a) T 17(a) I 8 U	9(d)(2) MP 9(d)(2) I	17(a) I 7(a)(1) U 7(c) U	17(a)(2) I 14(c) U 7 U 27(c) U	14(a) MP 17(a)(2) I 14(a) U	15(d) MP 15(d),(c) CD 15(d),(c) U		
PPPA				3 U				
FHSA	4(a)(f) CD 14(a) I 2(q)(1)(A),(B) U			14(a) I 3(b) U 2(P) U		15(a)(1) MP 15(a)(2) CD 6 U 15(a) U		14(a) I 3(a)(2) U 2(a)(2) U
OSHA	13(a) W		5(a) W 6(a) W 6(a)(5) W 6(c)(1) W 20(a)(3) W 22 W	6(a)(7) W 6(b)(7) W			6(b)(7) W 8(c)(3) W 13(c) W 20(a)(b) W	13 W
HMTA	105(a) T	105(a) T	106(a) T	105(a) T	106(b)(c) T			111(b) T
FFDCA	301(a)(d) CD 801(a) I		801(a) I 401 U 406 U 408 U	801(a) I 403 U 502 U 506(d) U 512(d)(1) U 802 U	510 MP 505 CD 512 CD 505 U 512 U 706 U	304 U		505(e) U 512(e)(1) U
	LEGEND: MP: MANUFACTURING, PROCESSING CD: COMMERCIAL DISTRIBUTION EE: EMISSIONS/EFFLUENTS T: TRANSPORTATION I: IMPORTS U: END USE (PRODUCTS) D: DISPOSAL/STORAGE W: WORKPLACE EXPOSURE							

CHART 3	MANUFACTURING/ PROCESSING	COMMERCIAL DISTRIBUTION	EMISSIONS, EFFLUENTS	TRANS-PORTATION	IMPORTS	END USE (PRODUCTS)	STORAGE/ DISPOSAL	WORKPLACE EXPOSURE
CAA	211(c) P 111(b),(c) GS 165(a) RC 172(b)(6) RC	211(c) P 211(a),(b) RC 203(a)(1) RC	110(a)(2) QL 108 GS 109 GS 111(a) GS 112(b)(1) GS 160-169 GS 202 GS 303 IH 311 IH			202(a)(1) GS 204 RC 211(b)(2) RC		
CWA	301 QL 302 QL 304 QL 306 QL		306 P 307(a)(2) P 311(b)(1) P 301 QL 307(a)(2) QL 311(b)(1) GS 307(a)(2) GS 303; 304 GS 306 GS 301(b)(2) RC 401; 402 RC 311(b)(2) N 504 IH	311 GS			307(a) GS 405 RC	
FIFRA	7(a) RC	6 P 12(a) P 13(a) P 3(a) RC 13(a),(b) RR 6 RC 12 RR 6(c) IH		19(b) GS	17(c) P 17(c) LP 17(c) RC 12(a) P 13(a) P 6 P 13 RR 6(c) IH	6 P 12(a) P 13(a) P 3(d) GS 3(c)(5) LP 3(a) RC 4(a) RC 5; 6; 18 RC 12; 13 RR 8(c) IH	19 GS	
RCRA	3002(2),(3) GS		7003 IH	3003 GS 3003(a) LP 3003 RC 7003 IH			3004 P 3006 P 3002(2),(3) LP 3004 LP 3004 GS 3006 GS 4004 GS 1008 GS 3005 RC 7003 IH	
SDWA			1424(a) P 1412 GS 1421 GS 1421 RC 1424(b) RC 1431 IH			1431(a) IH		
TSCA	5(a),(f) P 6(a) P 5(f) QL 6(a) QL 6(b) GS 6(a)(3) LP 6(a)(7) N 7 IH	6(a)(1)(A) P 6(a)(2)(A) P 6(a)(1)(B) QL 6(a)(2)(B) QL 6(a)(3) LP 7 IH		6(a)(1) P 6(a)(2) P 6(a)(1) QL 6(a)(2) QL 6(a)(3) LP 7 IH	13(a),(b) P 6(a)(5) QL 6(a)(2) GS 13(a) LP 13(a) IH	6(a)(2) P 6(a)(5) P 6(a)(5) QL 6(a)(5) GS 6(a)(3) LP 6(a)(7) RR 7 IH	6(a)(6) P 6(a)(6) GS 6(a)(3) LP 7 IH	
CPSA	19(a) P 9(d)(2) QL 14(a) RC 15(d) RR	8 P 19(a) P 15(d),(c) RR 12 IH		8 P 19(a) P	17(a) P 17(a)(1) GS 9(d) QL 17(a)(2) LP 17(a)(2) RC 17(a)(3) IH	8 P 7(a)(1) GS 7(c) GS 14(c) LP 14(a) RC 15(d),(c) RR 15 N 12 IH		
PPPA						3 LP 3 LP		
FHSA	15(a) RR	4(a)(f) P 15(a)(2) RR			14(a) P 14(a) LP 14(a) IH	2(q)(1)(A),(B) P 3(b);2(p) LP 6 RR 15(a) RR 3(e) IH		
OSHA								13(a) P 6(a) GS 6(b) GS 6(c) GS 20(a) GS 22 GS 6(b)(7) N 13 IH
HMTH				105(a) QL 106(a) GS 105(a) LP 106(b) RC 106(c) RC 111(b) IH				20(a)(2) GS 8(c)(3) N 13(c) N 20(a)(6) N
FFDCA	510 RC	301(a),(d) P 505 RC 512 RC			801(a) P 801(a) GS 801(a) LP	401 GS 406 GS 408 GS 403 LP 502 LP 505(d) LP 512(d) LP 602 LP 505 RC 512 RC 706 RC 304 RR 505(a) IH 512(a)(1) IH		

LEGEND

P	PROHIBITIONS
QL	QUANTITY LIMITATIONS
GS	GUIDELINES, STANDARDS
LP	LABELING, PACKAGING
RC	REGISTRATION, CERTIFICATION
RR	RECALL, REPLACE, REPURCHASE
N	NOTICE REQUIREMENTS
IH	IMMIMENT HAZARDS

CHART 4	TSCA	RCRA	FIFRA	CAA	CWA	SDWA	FFDCA	OSHA	CPSA	FHSA	PPPA	HMTA
TESTING REQUIREMENTS	4 5(a) 6(a)(4) 30	3001 3002	3(c)(1)(D) 5(d)	111(j)(1)(A) 211(b)(1)(A)		1412 1421	409(b)(2) 505(b) 505(i) 512(b)	6(b)(7) 20(a)(5)	7(d)(3)(A) 14(a) 14(b)			
MONITORING (COMPLIANCE, EXPOSURE, HEALTH EFFECTS)	6(a)(4) 6(b) 10(a)	3004(2)	3 20(b),(c)	110(a)(2)(C) 110(a)(2)(F)(ii) 114(a)(1) 165(a)(7) 319	104(a)(5) 308(a)(8) 401(d)	1413(a)(2) 1421(b)(1)(C) 1445(a)	505 512	6(b)(7) 8(c)(3) 20(a)(5)				106(a)
INSPECTIONS RECORDS/ PREMISES	8(c) 11(a),(b)	3007	8(b) 9	114(a)(2)	308(a)(B) 311(m)	1413(a)(2) 1421(b)(1)(C) 1445(b)(1)	505 512 702 704	8(a) 8(c) 8(g)(2) 18(c)(3) 19(a)(3) 19(d)	7(d)(3)(C) 16(a) 16(b)	11 12 14		109(c)
PROVISIONS FOR TEST DATA SUBMISSION (AS PART OF REGISTRATION, CERTIFICATION, OR PERMIT PROCESS)	4(g) 5(h)	3004(7) 3005 3010(a)	3 5 6(a)(2)	110(a)(2)(D) 110(a)(4) 110(j) 111(j)(1)(A) 112(c)(1)(B)(ii) 165 165(a)(8) 172(b)(6) 173 211(b)(2)	301(c),(g) 401(a) 402 403(a)	1421(b)(1)(A) 1422(b)(1)(A)	408 409 505 512 706		10 27(e)			106(b),(c) 107
NOTIFICATION REQUIREMENTS (PREMANUFACTURE, PREMARKET, ETC)	5 6(a)(7) 6(b)(2) 7(b)(2) 8(e) 12(b)	3002(4) 3010	12(a)(1)(P) 17(b)	111(j)(1)(A) 165	311(b)(5) 311(c)(2)(D) 402(b)(8) 402(d)	1414			13(a) 14(a)(1) 15(b) 15(c) 27(e) 14(c)(3)			
SUBMISSION OF REPORTS (OPERATIONS, OUTPUTS, HEALTH/ENVIR. EFFECTS, REQUIRED STUDIES)	4(b)(1) 5(b)(2)(A) 5(d)(1)(A) 8(a)(2) 8(d)	3002(6) 3004(2) 3005(b)	3(c)(2) 5(d) 6(a)(2) 17(c) 11(a) 7	110(a)(2)(C) 110(a)(2)(F)(ii) 110(a)(4) 111(j)(1)(A) 165(a)(6) 165(e)(1) 172 211(b)(2)(B)	305 308(a)(A)(ii)	1413	505 512	8(c)(2) 18(c)(7) 18(c)(8) 20(a)(5) 19(a)(5)	27(e)			109(c)
INTERAGENCY COOPERATION FOR INFORMATION AND OTHER PURPOSES	4(b)(2)(A) 6(c) 8(a)(3)(B) 9 9(d) 10 10(b)(1) 10(g) 26 27	1006 3003 6003 8001(a) 8001(b) 8002(f) 8003(f)	3 6(b) 17(d) 21(a) 25(a)(2) 19 20 28	103 323(e) 402 (PL 95-95)	102(a) 104 105 115 501(b)	1442 1412	702(c) 702(d) 707	7(c)(1) 8(c)(3) 20 24 19(a)(4) 19(a)(5) 21	29	10(b)		105(b)

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